

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552596	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED R 12/29/2010
NAME OF PROVIDER OR SUPPLIER ONTARIO DIALYSIS CENTER, INC			STREET ADDRESS, CITY, STATE, ZIP CODE 1001 WEST 6TH STREET ONTARIO, CA 91764		
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{V 000}	INITIAL COMMENTS The following reflects the findings of the California Department of Public Health during a revisit survey conducted on 12/29/10. Representing the Department: Octavio Relopez, HFEN Census: 89 Sample Size: 8 Unsampled: 17	{V 000}			
{V 110}	494.30 CFC-INFECTON CONTROL This CONDITION is not met as evidenced by: Based on interview and record review it was determined that the facility did not meet the Condition of Participation for Infection Control by failing to: 1. Ensure that the patients' Hepatitis B serological (blood test) status were known before admission to the hemodialysis unit. In addition, the facility failed to ensure that the patients' Hepatitis B tests results were promptly reviewed and managed appropriately based on their testing results. (Refer to V 124) 2. Offer and provide Hepatitis B vaccination to all susceptible patients and staff promptly prior to performing direct patient care, and for the patients, prior to admission to the hemodialysis unit. (Refer to V 126) The cumulative effect of these systemic practices had the potential to result in the transmission of Hepatitis B and other blood borne infections within the facility placing the patients' health and	{V 110}			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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

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{V 110}	Continued From page 1 safety at risk. The facility failed to ensure compliance with Federal Regulations for the Condition of Participation: Infection Control.	{V 110}			
{V 124}	494.30(a)(1)(i) IC: HBV: TEST ALL,REV RESULTS/STATUS B4 ADMIT Routine Testing for Hepatitis B The HBV serological status (i.e. HBsAg, total anti-HBc and anti-HBs) of all patients should be known before admission to the hemodialysis unit. Routinely test all patients [as required by the referenced schedule for routine testing for Hepatitis B Virus]. Promptly review results, and ensure that patients are managed appropriately based on their testing results. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure that the Hepatitis B Virus (HBV) serological status (blood test results) of one (1) unsampled of 17 unsampled patients (Patients 12) were known before admission to the hemodialysis unit. The facility failed to ensure 18 patients' (Sampled Patients 2, 5, 6, 8, and unsampled Patients 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22) Hepatitis B tests results were promptly reviewed and managed appropriately based on their testing results. These failures had the potential to result in the transmission of Hepatitis B infection among dialysis patients in a universe of 89 patients. Findings: During a record review on 12/29/10, Patient 12's medical record showed that she had the first dialysis treatment in the facility on 11/2/10 and	{V 124}			

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{V 124}	<p>Continued From page 2</p> <p>was admitted in the facility on 11/12/10.</p> <p>The laboratory (lab) test results dated 11/15/10 documented that Patient 12's Hepatitis B surface antibody (HBsAB- test used to determine amount of immunity) level was 0.6 which indicated that the patient was non-immune and susceptible to Hepatitis B infection (A level of less than 10.0 is considered non-immune and susceptible to Hepatitis B infection). There was no prior lab test result and/or documentation found to indicate that the patient's Hepatitis B immune status had been pre-screened before beginning dialysis treatment and admission to the facility on 11/12/10.</p> <p>Further record review indicated that Patient 12 had not been offered and vaccinated immediately upon admission. There was no documentation found in the facility's "Hepatitis B Vaccination Tracking Form" for 2010 to indicate that the patient's non-immune status had been reviewed and had received the vaccine.</p> <p>According to the facility's Plan of Correction (POC) dated 12/2/10, "Routine Hepatitis B virus testing will be conducted, results will be promptly reviewed and documented (in the tracking log) with further plan of action if required... to help ensure that patients are managed appropriately based on their tests results... "</p> <p>A review of the facility's Hepatitis B Vaccination Tracking Form showed the following documentation:</p> <p>16 patients including newly admitted patients (Patients 2, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 21, 22) who were non-immune and susceptible to Hepatitis B infection had not</p>	{V 124}			

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{V 124}	<p>Continued From page 3</p> <p>received the Hepatitis B vaccine. No documentation was found to indicate the reason why the patients did not received the vaccine.</p> <p>Three (3) patients including a new admit patient (Patients 12, 19 and 20) did not have a vaccination record or Hep B test results prior to admission in the facility to determine their immunity status. No documentation was found to indicate the reason why the patients did not have the Hepatitis B test results.</p> <p>3 patients (Patients 23, 24 and 25) had received the first dose of the vaccine in the past 3 months on 9/22/10 and had not been followed up with the 2nd, 3rd, and 4th dose to complete the vaccine series according to vaccination schedule. No documentation was found to indicate why vaccine series had not been followed up or completed.</p> <p>According to the "MMWR (Morbidity and Mortality Weekly Report)- Recommended Adult Immunization Schedule," dated January 15, 2010/Vol. 59/ No. 1, page 4, the following were noted:</p> <p>"Adult patients receiving hemodialysis... should receive... 2 doses of 20 mg/ml (Engerix- B) administered simultaneously on a 4- dose schedule at 0 (first dose), 1 (2nd dose given in 1 month after the 1st dose), 2 (third dose given in 2 months after the 2nd dose), and 6 months (4th dose given in 6 months after the 3rd dose)."</p> <p>During an interview with the facility administrator (FA) on 12/29/10, at 12:15 PM, the FA reviewed Patient 12's medical record and the Hepatitis tracking form and was unable to find documentation which indicated that the patient 12</p>	{V 124}			

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{V 124}	Continued From page 4 had been pre-screened for Hepatitis B prior to admission or had been offered and received the vaccine promptly after admission in the facility. The FA acknowledged that there was no documentation found to indicate that the above 16 patients who were non-immune to Hepatitis B had not received the vaccine; 3 patients did not have Hepatitis B test results or vaccination record; and 3 patients who had received the first dose of the vaccine had not been followed up to complete the vaccine series.	{V 124}			
{V 126}	494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF Hepatitis B Vaccination Vaccinate all susceptible patients and staff members against hepatitis B. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to offer and vaccinate 3 susceptible staffs (PCT 1, 2, and RN 2) and 16 patients (Patients 2, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 21, 22) against Hepatitis B which had the potential to result in patients and staff contracting and transmitting Hepatitis B infection to other patients and staff. Findings: 1. During a review of the employee files of new hired staff (PCT 1, 2 and RN 2) on 12/29/10, the lab test results showed that PCT 1 and 2 were non-immune and susceptible to Hepatitis B infection. No evidence of documentation was found in the employee files which indicated that PCT 1 and 2 had been offered and vaccinated against Hepatitis B infection. PCT 1 and 2 had been working in the treatment area providing	{V 126}			

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{V 126}	<p>Continued From page 5 direct patient care.</p> <p>RN 2 who was hired on 12/16/10 did not have lab test results to determine her immunity status to Hepatitis B virus (HBV) prior to providing direct patient care. RN 2, had been allowed to work in the treatment area providing direct patient care.</p> <p>A review of the facility's POC dated 12/2/10, the following were noted:</p> <p>"It shall be implemented that all new hire(s) have lab work done within the year, including Hepatitis B, prior to employment..."</p> <p>During an interview with the FA on 12/29/10, at 3:18 PM, the FA reviewed the employee files of PCT 1, PCT 2 and RN 2 and confirmed the the findings. The FA acknowledged that there was no documentation found which indicated that PCT 1 and 2 had been offered and vaccinated against Hepatitis B infection, and that no test result was found to determine RN 2's immunity status to Hepatitis B prior to providing direct patient care.</p> <p>2. During a record review on 12/29/10, Patient 12's lab test results dated 11/15/10 documented that the patient's HBsAB level was 0.6 which indicated that the patient was non-immune and susceptible to Hepatitis B infection. (A level of less than 10.0 is considered non-immune and susceptible to HBV). There was no documentation found to indicate that Patient 12 had been offered and vaccinated immediately upon admission.</p> <p>A review of the facility's Hepatitis B Vaccination Tracking Form showed the following documentation:</p>	{V 126}			

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{V 126}	Continued From page 6 16 patients including newly admitted patients (Patients 2, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 21, 22) who were non-immune and susceptible to Hepatitis B infection had not received the Hepatitis B vaccine. No documentation was found to indicate the reason why the patients did not received the vaccine. During an interview with the FA on 12/29/10, at 12:15 PM, the FA reviewed Patient 12's medical record and the Hepatitis tracking form and was unable to find documentation to indicate that the above 16 patients who were non-immune to Hepatitis B had been offered and vaccinated against Hepatitis B infection.	{V 126}			
{V 502}	494.80(a)(1) PA-ASSESS CURRENT HEALTH STATUS/COMORBIDS The patient's comprehensive assessment must include, but is not limited to, the following: (1) Evaluation of current health status and medical condition, including co-morbid conditions. This STANDARD is not met as evidenced by: Based on interview and record review, the facility's interdisciplinary team (IDT) failed to ensure that the patient comprehensive assessment included evaluation of current health and medical status including co-morbid conditions (additional diseases) for one of 8 sampled patients (Patient 7) which resulted in failure to develop an appropriate patient comprehensive care plan and meet the patients' individual health care needs and goals.	{V 502}			

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{V 502}	<p>Continued From page 7</p> <p>Findings:</p> <p>On 12/28/10, a review of Patient 7 ' s medical record was conducted. The IDT comprehensive patient assessment dated 2/12/08 indicated that patient was admitted in the facility on 9/15/08 and had diagnosis that included end stage renal disease (ESRD).</p> <p>Patient 7's lab test results showed that the patient had an abnormally low and unstable blood count levels indicating a severe anemia. The test results showed that the patient's hemoglobin (Hgb- a blood component that transport oxygen to body tissues.) level dropped from an abnormally low level of 7.8 on 11/9/10 to a lower level of 7.0 on 12/10/10 (Normal adult hemoglobin level = 13.0-17.0). Patient 7's hospitalization record dated 3/15/10 showed that he was sent to the hospital for blood transfusion due to "severe anemia (a low blood count that can make you tired and short of breath)."</p> <p>A review of the facility's "Re-assessment Log" showed that Patient 7's comprehensive patient assessment completion date was on 8/12/09. There was no current comprehensive assessment found that reflects the patient's current health and medical status including co-morbid conditions which included "severe anemia."</p> <p>During an interview with RN 3 on 12/28/10, at 11:10 AM, RN 3 reviewed Patient 7's medical record and was unable to find the patient's current comprehensive assessment. RN 3 stated, "I'm only part time RN here, but I help with paperwork.... They are really behind with (patient) assessments and care plans, that's why I am</p>	{V 502}			

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{V 502}	Continued From page 8 here."	{V 502}			
{V 506}	<p>494.80(a)(3) PA-IMMUNIZATION/MEDICATION HISTORY</p> <p>The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>Immunization history, and medication history.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure that the patient's comprehensive assessment for 1 sampled (Patient 2) and 2 unsampled (Patients 12 and 13) patients included immunization history which included tuberculosis (TB- a disease of the lung) and Hepatitis B screening prior to admission in the facility in a universe of 89 patients. This resulted in the facility's failure to develop an appropriate plan of care to manage the patient's immunization problem and had the potential to result in acquiring and/or transmitting the disease to other patients and staff.</p> <p>Findings:</p> <p>1. On 12/28/10, a review of Patient 13's medical record showed that the patient was admitted in the facility on 11/12/10 and had diagnoses that included ESRD. Patient 13 had the first hemodialysis treatment in the facility on 11/3/10.</p> <p>A review of Patient 13's lab test results and the PPD (purified protein derivative) skin test record log showed no evidence of a tuberculin skin test (TST- test to determine exposure to TB) and/or a chest x-ray had been completed, reviewed and</p>	{V 506}			

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{V 506}	<p>Continued From page 9</p> <p>evaluated before admission. There was no documentation found which indicated that the IDT had developed a plan of care to address the problem. No evidence was found to indicate that Patient 13 had been screened for tuberculosis prior to admission in the facility.</p> <p>During an interview with the FA on 12/28/10, at 3:15 PM, the FA reviewed Patient 13's medical record and the facility's immunization log and was unable to find documentation which indicated that the patient had been screened for TB prior to admission in the facility. The FA further acknowledged that the IDT had failed to develop a plan of care to address the patient's immunization status.</p> <p>2. On 12/28/10, a review of Patient 2's medical record showed that the patient was admitted in the facility on October 2010 with diagnoses that included ESRD. Patient 2 had the first hemodialysis treatment in the facility on 10/1/10.</p> <p>A review of Patient 2's lab test results and the PPD (purified protein derivative) skin test record log showed no evidence that a tuberculin skin test (TST- test to determine exposure to TB) and/or a chest x-ray had been completed, reviewed and evaluated before admission. There was no evidence found to indicate that Patient 2 had been screened for tuberculosis prior to admission in the facility.</p> <p>During an interview with the FA on 12/28/10, at 3:15 PM, the FA reviewed Patient 2's medical record and the facility's immunization log and was unable to find documentation which indicated that the patient had been screened for TB prior to admission in the facility. The FA further</p>	{V 506}			

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{V 506}	<p>Continued From page 10</p> <p>acknowledged that the IDT had failed to develop a plan of care to address the patient's immunization status.</p> <p>3. During a record review on 12/29/10, Patient 12's medical record showed that the patient was admitted in the facility on 11/12/10 and had diagnoses that included ESRD. Patient 12's had the first hemodialysis treatment in the facility on 11/2/10.</p> <p>The laboratory (lab) test results showed no prior lab test result and/or documentation to indicate that the patient had been pre-screened for Hepatitis B before beginning dialysis treatment and admission in the facility on 11/12/10. Patient 12's lab test results dated 11/15/10 showed that the patient's Hepatitis B surface antibody (HBsAB- test used to determine amount of immunity) level was 0.6 which indicated that the patient was non-immune and susceptible to Hepatitis B infection (A level of less than 10.0 is considered non-immune and susceptible to Hepatitis B infection).</p> <p>There was no documentation found in the patient's medical record to indicate that the IDT had developed a comprehensive plan of care to manage the patient's non-immune status.</p> <p>During an interview with the facility administrator (FA) on 12/29/10, at 12:15 PM, the FA reviewed Patient 12's medical record and the Hepatitis tracking form and was unable to find documentation which indicated that the patient 12 had been pre-screened for Hepatitis B prior to admission or had been offered and received the vaccine promptly after admission in the facility. The FA was unable to find documentation which</p>	{V 506}			

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{V 506}	Continued From page 11 indicated that the IDT had developed a comprehensive plan of care that addressed the patient's non-immune status to Hepatitis B infection.	{V 506}			
{V 516}	494.80(b)(1) PA-FREQUENCY-INITIAL-30 DAYS/13 TX An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure that initial comprehensive assessments were conducted on new patients within the latter of 30 calendar days or 13 hemodialysis treatments beginning with the first dialysis session for 2 unsampled patients (Patients 12 and 13) in a universe of 89 patients. This resulted in failure to provide prompt health care needs and services which included the management of the patients' immunization status. Findings: 1. During a record review on 12/28/10, Patient 13's medical record indicated that she was admitted in the facility on 11/12/10 with diagnosis that included ESRD. Patient 13's first dialysis treatment session was on 11/3/10. There was no comprehensive patient assessment and plan of care was found in the patient's medical record. A review of Patient 13's lab test results dated 11/17/10 showed that the patient's HBsAB level was 0.7 which indicated that the patient was	{V 516}			

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{V 516}	<p>Continued From page 12</p> <p>non-immune and susceptible to Hepatitis B infection. (A level of less than 10.0 is considered non-immune and susceptible to HBV). No documentation was found to indicate that Patient 12 had been offered and vaccinated immediately upon admission.</p> <p>There was no comprehensive care plan found which included management of the patient's non-immune status to Hepatitis B infection.</p> <p>During an interview with the FA on 12/28/10, at 9:40 AM, the FA reviewed the patient's medical record and was unable to find documentation which indicated that the patient's comprehensive assessment had been completed. The FA acknowledged that the IDT should have completed the patient's comprehensive assessment.</p> <p>2. During a review of Patient 12's medical record on 12/29/10, it was noted that the patient was admitted in the facility on 11/12/10 with diagnoses that included ESRD and severe anemia. The patient's first hemodialysis treatment session was completed on 11/2/10.</p> <p>A review of the patient's initial comprehensive assessment showed that all portions of the assessment had not been completed with the exception of the Social Services assessment dated 11/19/10.</p> <p>A review of Patient 12's lab test results dated 11/15/10, documented that the patient's HBsAB level was 0.6 which indicated that the patient was non-immune and susceptible to Hepatitis B infection. No documentation found to indicate that Patient 12 had been offered and vaccinated</p>	{V 516}			

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552596	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED R 12/29/2010
NAME OF PROVIDER OR SUPPLIER ONTARIO DIALYSIS CENTER, INC			STREET ADDRESS, CITY, STATE, ZIP CODE 1001 WEST 6TH STREET ONTARIO, CA 91764		
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{V 516}	Continued From page 13 immediately upon admission. There was no comprehensive care plan found which included management of the patient's non-immune status to Hepatitis B infection. During an interview with the FA on 12/29/10, at 9:15 AM, the FA reviewed the patient's medical record and was unable to find documentation which indicated that the patient's comprehensive assessment had been completed and that a comprehensive care plan had been developed. The FA acknowledged that the IDT should have completed the patient's comprehensive assessment.	{V 516}			
{V 640}	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. This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to immediately correct identified problems that threaten the health and safety of patients by failing to: 1. Conduct Hepatitis B testing for new hired staffs (PCT 1 and 2, RN 2) to determine their immunization status prior to providing direct patient care. 2. Conduct screening tests for TB and Hepatitis B, and to vaccinate all susceptible patients promptly prior to receiving hemodialysis treatment and admission to the facility. These failures had the potential to result in	{V 640}			

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{V 640}	<p>Continued From page 14</p> <p>cross-contamination between potentially infected and non-infected patients and staff.</p> <p>Findings:</p> <p>1. During a review of the facility's Plan of Correction (POC) dated 12/2/10, the POC for the Quality Assessment and Performance Improvement (QAPI) and Hepatitis B vaccination included the following:</p> <p>"... The IDT is now working with each other in a structured scheduled meeting bi-weekly... currently the facility does not have any patients that have been found to be susceptible to the Hepatitis B infection..."</p> <p>During review of the employee files of new hired staff (PCT 1, 2 and RN 2) on 12/29/10, the lab test results showed that PCT 1 and 2 were non-immune and susceptible to Hepatitis B infection. No evidence of documentation was found in the employee files which indicated that PCT 1 and 2 had been offered and vaccinated against Hepatitis B infection. PCT 1 and 2 had been working in the treatment area providing direct patient care.</p> <p>RN 2 who was hired on 12/16/10 did not have lab test results to determine her immunity status to Hepatitis B virus (HBV) prior to providing direct patient care. RN 2, had been allowed to work in the treatment area providing direct patient care.</p> <p>A review of the facility's POC dated 12/2/10, the following were noted:</p> <p>"It shall be implemented that all new hire(s) have</p>	{V 640}			

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{V 640}	<p>Continued From page 15</p> <p>lab work done within the year, including Hepatitis B, prior to employment..."</p> <p>During an interview with the FA on 12/29/10, at 3:18 PM, the FA reviewed the employee files of PCT 1, PCT 2 and RN 2 and confirmed the the findings. The FA acknowledged that there was no documentation found which indicated that PCT 1 and 2 had been offered and vaccinated against Hepatitis B infection, and that no test result was found to determine RN 2's immunity status to Hepatitis B prior to providing direct patient care.</p> <p>2. a. During a record review on 12/29/10, Patient 12's lab test results dated 11/15/10 documented that the patient's HBsAB level was 0.6 which indicated that the patient was non-immune and susceptible to Hepatitis B infection. (A level of less than 10.0 is considered non-immune and susceptible to HBV). There was no documentation found to indicate that Patient 12 had been offered and vaccinated immediately upon admission.</p> <p>A review of the facility's Hepatitis B Vaccination Tracking Form showed the following documentation:</p> <p>16 patients including newly admitted patients (Patients 2, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 21, 22) who were non-immune and susceptible to Hepatitis B infection had not received the Hepatitis B vaccine. No documentation was found to indicate the reason why the patients did not received the vaccine.</p> <p>During an interview with the FA on 12/29/10, at 12:15 PM, the FA reviewed Patient 12's medical record and the Hepatitis tracking form and was</p>	{V 640}			

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{V 640}	<p>Continued From page 16</p> <p>unable to find documentation to indicate that the above 16 patients who were non-immune to Hepatitis B had been offered and vaccinated against Hepatitis B infection.</p> <p>b. On 12/28/10, a review of Patient 13's medical record showed that the patient was admitted in the facility on 11/12/10 and had diagnoses that included ESRD. Patient 13 had the first hemodialysis treatment in the facility on 11/3/10.</p> <p>A review of Patient 13's lab test results and the PPD (purified protein derivative) skin test record log showed no evidence of a tuberculin skin test (TST- test to determine exposure to TB) and/or a chest x-ray had been completed, reviewed and evaluated before admission. There was no documentation found which indicated that the IDT had developed a plan of care to address the problem. No evidence was found to indicate that Patient 13 had been screened for tuberculosis prior to admission in the facility.</p> <p>During an interview with the FA on 12/28/10, at 3:15 PM, the FA reviewed Patient 13's medical record and the facility's immunization log and was unable to find documentation which indicated that the patient had been screened for TB prior to admission in the facility.</p> <p>c. On 12/28/10, a review of Patient 2's medical record showed that the patient was admitted in the facility on October 2010 with diagnoses that included ESRD. Patient 2 had the first hemodialysis treatment in the facility on 10/1/10.</p> <p>A review of Patient 2's lab test results and the PPD (purified protein derivative) skin test record log showed no evidence that a tuberculin skin test</p>	{V 640}			

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{V 640}	Continued From page 17 (TST- test to determine exposure to TB) and/or a chest x-ray had been completed, reviewed and evaluated before admission. There was no evidence found to indicate that Patient 2 had been screened for tuberculosis prior to admission in the facility. During an interview with the FA on 12/28/10, at 3:15 PM, the FA reviewed Patient 2's medical record and the facility's immunization log and was unable to find documentation which indicated that the patient had been screened for TB prior to admission in the facility.	{V 640}			