

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

PRINTED: 05/31/2011
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552504	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 02/25/2011
NAME OF PROVIDER OR SUPPLIER TOKAY DIALYSIS CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 312 SOUTH FAIRMONT AVENUE, SUITE A LODI, CA 95240		
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V 000	INITIAL COMMENTS The following reflects the findings of the California Department of Public Health during an End Stage Renal Disease (ESRD) Dialysis Clinic Re-certification survey conducted from 2/22/2011 through 2/25/2011. Representing the Department: HFES #22968 HFES #20435 HFEN #28347 Abbreviations: ADM - Administrator (alternate) CHT - Certified Hemodialysis Technician CSS - Clinical Services Specialist DFR - Dialysate Flow Rate (expressed in ml/minute) ml - milliliter NFPA - National Fire Protection Association RN - Registered Nurse	V 000			
V 113	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station. This STANDARD is not met as evidenced by: Based on observation, staff interview, and policy and procedure review, the facility failed to ensure facility staff follow hand hygiene procedures while caring for dialysis patients or touching equipment. This failure occurred in the following ways: (a) staff did not sanitize hands between removing	V 113		3/30/11	

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

TITLE

(X6) DATE

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

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V 113	<p>Continued From page 1</p> <p>gloves and putting on a new pair of gloves; (b) staff did not sanitize hands after removing gloves and before touching a clean area; and (c) staff moved between patients and/or stations without changing gloves and/or sanitizing hands between each patient or station. Not following procedures for hand hygiene had the potential to increase patient risk to infections and cross contamination.</p> <p>Findings:</p> <p>On 2/22/11 at 11:50 a.m., during an observation at dialysis station 7, CHT1 reset the dialysis machine alarm with an ungloved hand. Several minutes later, a physician pushed the screen selection buttons on the same dialysis machine with an ungloved hand. After touching the dialysis machine, the physician proceeded to type on the clean chair-side computer keyboard without prior washing or performing hand hygiene (e.g, using hand sanitizer).</p> <p>During further observations at 12:15 p.m., CHT1 put on gloves and assisted the patient at station 7. CHT1 proceeded to type on the clean chair-side computer keyboard while still wearing the same, used gloves.</p> <p>On 2/24/11 at 8:05 a.m. , during observations at dialysis station 5, CHT1 was wearing gloves while taking a patient off dialysis. CHT1 removed the gloves, did not wash or sanitize hands and proceeded to type on the clean chair-side computer keyboard. At 8:20 a.m., CHT1 removed used gloves and put on clean gloves without washing or performing hand hygiene in between tasks. CHT1 assisted the patient at station 5 then went to station 7 to assist that patient without</p>	V 113			

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V 113	<p>Continued From page 2</p> <p>changing gloves, washing, or performing hand hygiene between each patient contact to prevent cross contamination.</p> <p>On 2/24/11 at 8:40 a.m., during care observations near dialysis station 12, CHT2 wore gloves and wiped a wet spot on the floor with a paper towel. Then CHT2 removed the gloves and proceeded to use the clean chair-side keyboard without washing or performing hand hygiene.</p> <p>On 2/24/11 at 8:55 a.m., CHT1, wearing gloves, performed the manual conductivity and pH test (test for acidity) on the dialysis machine at station 5. CHT1 removed the gloves and proceeded to use the clean chair-side computer without washing or performing hand hygiene.</p> <p>A 2/24/11 review of the facility's policy titled INFECTION CONTROL FOR DIALYSIS FACILITIES (Policy: 1-05-01, last revision date September 2010) there is stipulation in pertinent parts: "Hand hygiene is to be performed . . . prior to gloving, after removal of gloves, . . . after patient and dialysis delivery system contact, between patients even if the contact is casual, before touching clean areas . . . Physicians . . . are to follow these same requirements for glove use and hand hygiene" and "Teammates will wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station . . ." The policy further stipulates: "The ChairSideSnappy cart, monitor and keyboard are considered clean areas. . . gloves are to be removed and hands washed or alcohol based hand rubs used before and after touching the keyboard."</p>	V 113			

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V 113	Continued From page 3 During an interview and concurrent infection control policy review on 2/24/11 at 12 p.m., the ADM (alternate) confirmed policy was not followed and acknowledged hand washing or hand hygiene must be performed every time gloves are removed and in between patients. She also verified the chair-side computer keyboard is considered a clean item.	V 113			
V 119	494.30(a)(1)(i) IC-SUPPLY CART DISTANT/NO SUPPLIES IN POCKETS If a common supply cart is used to store clean supplies in the patient treatment area, this cart should remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood. Such carts should not be moved between stations to distribute supplies. Do not carry medication vials, syringes, alcohol swabs or supplies in pockets. This STANDARD is not met as evidenced by: Based on observation, interview and facility policy review, the facility failed to store clean supplies at a sufficient distance from patient dialysis stations to avoid cross contamination when an open medical supply cart was located next to a hand washing sink adjacent to dialysis station 12. Findings: During the Initial Tour of the facility on 2/22/11 at 11:15 a.m., an open, two tiered, rolling supply cart was observed next to the hand washing sink, against the wall adjacent to dialysis station 12. The cart held a variety of clean supplies such as sterile gauze, Band-Aids, and gloves. There was	V 119		3/30/11	

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V 119	Continued From page 4 a sign posted on the wall above the cart with the words "Supply Cart" and an arrow pointing downwards to where the cart was placed. The cart was positioned two to three feet to the right of the patient's dialysis chair. During an interview on 2/22/11 at 1:50 p.m., CHT3 was asked to describe their understanding of the "splash zone." CHT3 described the "splash zone" as the area surrounding a patient station and about 5 feet away from the patient/dialysis chair. When asked if the supply cart was at risk for body fluid exposure, CHT3 said yes "I've seen blood shoot clear across the room...." In an interview 2/22/11 at 3:45 p.m., RN1 was also asked to explain their understanding of the "splash zone. RN 1 stated he/she thought the "splash zone" or "exposure area" was about 6 feet from the patient's dialysis chair. In a concurrent interview, the CSS and RN1 both looked at the supply cart adjacent to the hand washing sink next to station 12 and agreed that it located close enough to be at risk for becoming contaminated with blood and/or other fluids. Review of the facility policy titled: INFECTION CONTROL FOR DIALYSIS FACILITIES (Last reviewed 9/10; Policy 1-05-01) revealed the following under item 42: "If a common supply cart is used to store clean supplies in the patient treatment area, this cart is to remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood."	V 119			
V 402	494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY	V 402		4/11/11	

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V 402	<p>Continued From page 5</p> <p>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>This STANDARD is not met as evidenced by: Based on observation, staff interview, administrative document review and review of manufacturer's guidelines, the facility failed to maintain the dialysis center free from hazards to safety when:</p> <ol style="list-style-type: none"> Used and unused paint containers were stored in the janitor's closet adjacent to flammable objects and in violation of manufacturer's guidelines for safe storage. Stored items were in front and on top of the electrical panels in violation of NFPA guidelines regarding maintenance of electrical panels. <p>These failures increased the risk of preventable injury from hazards to staff, patients and visitors.</p> <p>Findings:</p> <ol style="list-style-type: none"> On 2/22/11 at 1:45 p.m., during the initial tour, the janitor's closet was noted to have opened and unopened paint cans stored next to paper products. Access to the janitor's closet was through a door located within the store room. The janitor's closet was equipped with a metal shelving unit that held many miscellaneous items such as toilet paper and paper towels. A used gallon of latex wall paint, with the top on, was stored on the shelf with toilet paper and other miscellaneous paper products. On this same 	V 402			

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V 402	<p>Continued From page 6</p> <p>shelf was a used aerosol orange paint container without the protective cap. Its label read "highly flammable". Three 1-gallon containers of unopened latex wall paint were stacked and stored on the floor near the door of the closet.</p> <p>On 2/23/11 at 10 a.m., during an interview, the ADM (alternate) and CSS stated that they did not know how long the paint containers were stored in the janitor's closet. They did not know if the janitor's closet was on the safety check-off tool used to monitor the facility for safety issues.</p> <p>On 2/25/11 at 10 a.m., during an interview, the Safety Officer stated he did not know how long the paint cans were stored in the janitor's closet. He stated he did not include the janitor's closet in the routine monitoring for safety.</p> <p>No documented evidence or log was provided that verified the janitor's closet and electrical panels in the store room were monitored for safety hazards.</p> <p>Review of the Material Safety Data Sheet provided by the manufacturer of the aerosol paint can indicated under "Handling and Storage Precautions - handle as an extremely flammable material..."</p> <p>Review of the manufacturer's instructions for the latex paint under "Handling and Storage" indicated "...Store in a cool, dry, well ventilated area away from sources of heat, combustible materials, and incompatible substances . . ."</p> <p>2. On 2/22/11 at 1:50 p.m., during the initial tour, electrical panels located along the back wall of</p>	V 402			

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V 402	Continued From page 7 the store room were obstructed by three 45-gallon containers. An artificial Christmas tree and three boxes of miscellaneous stored items were on top of the ledge of the large electrical panel. On 2/25/11 at 10 a.m., during an interview, the Safety Officer stated he did not know how long the Christmas items were stored on top of the electrical panel and did not know how long the 45-gallon containers were stored in front of the flat electrical panels. He stated he did not include the store room or electrical panels in the routine monitoring for safety. No documented evidence or log was provided that verified the janitor's closet and electrical panels in the store room were monitored for hazards to safety. Review of National Electrical Code NFPA 70 1999 edition under Article 110 Requirements for Electrical Installations, Spaces about Electrical Equipment indicated "... Sufficient access and working space shall be provided and maintained about all electric equipment to permit ready and safe operation and maintenance of such equipment. Enclosures housing electrical apparatus that are controlled by lock and key shall be considered accessible to qualified persons...(b) Clear Spaces. Working space required by this section shall not be used for storage..."	V 402			
V 409	494.60(d)(1) PE-ER PREP STAFF-INICIAL/ANNUAL/INFORM PTS The dialysis facility must provide appropriate training and orientation in emergency	V 409		4/30/11	

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V 409	<p>Continued From page 8</p> <p>preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following:</p> <p>(i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of-</p> <p>(A) What to do;</p> <p>(B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;</p> <p>(C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and</p> <p>(D) How to disconnect themselves from the dialysis machine if an emergency occurs.</p> <p>This STANDARD is not met as evidenced by: Based on interviews, facility document review, and policy review, the facility failed to provide annual disaster preparedness training and ensure staff had sufficient knowledge of emergency procedures to educate patients/designees about how to handle emergencies outside of the facility. This failure had the potential to increase risk of injury to patients and staff in the event of an external disaster.</p> <p>Findings:</p> <p>A 2/23/11, review of the facility's "Emergency Drill & Safety Binder" revealed there had been no drills</p>	V 409			

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V 409	Continued From page 9 in the last 12 months that addressed external disasters (e.g., earthquake or flooding). A 2/24/11 review of the facility's 11/29/10 Quality Improvement & facility Management Meeting (QIFMM) minutes revealed acknowledgement (by checkmark) that the facility had no specific disaster plan in place. The following statement was typed in: "FA [Facility Administrator] plan to focus on creating Facility Specific Disaster Plan January 2011.... " During a concurrent interview on 2/25/11 at 10:20 a.m., RN1 and RN2 were asked if the facility conducted external disaster training/drills. Both RNs confirmed they had not participated in a drill that addressed external disasters. RN2 added that she had not participated in an external disaster drill "in the one-and-one-half years I have been here." On 2/25/11 at 9 a.m., the CSS was questioned about whether the facility conducted annual external disaster drills. The CSS attempted to locate documentation regarding external disaster drills during the past 12-months (2010/2011) . However, the CSS was unable to produce documented evidence of facility staffs participation in annual external disaster preparedness drills as required.	V 409			
V 416	494.60(d)(4)(iii) PE-CONTACT LOCAL EOC ANNUALLY The facility must- (iii) Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an	V 416		4/30/11	

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V 416	<p>Continued From page 10 emergency.</p> <p>This STANDARD is not met as evidenced by: Based on interview and facility document review, the facility failed to contact the local disaster management agency at least annually to ensure that such agency was aware of the facility's needs in the event of an emergency. This failure had the potential to increase patient and staff risk for injury in the event of an emergency.</p> <p>Findings:</p> <p>A 2/24/11 review of the facility's disaster policy titled: DISASTER AND EMERGENCY PREPAREDNESS BUSINESS CONTINUITY PLAN (Last Reviewed 9/10; Policy 4-07-01) documented under item 20: "The facility must contact its local Emergency Operations Center (EOC) at least annually to ensure that the EOC is aware of the dialysis facility needs in the event of an emergency."</p> <p>A 2/24/11 review of the facility Quality Improvement & Facility Management Meeting (QIFMM) Minutes dated 11/29/10 revealed acknowledgement (by checkmark) that the facility had no specific disaster plan in place. The following statement was typed in: "FA [Facility Administrator] plan to focus on creating Facility Specific Disaster Plan January 2011"</p> <p>In a 2/25/11 9:35 a.m. interview, the CSS was questioned about communication/collaboration with local disaster management personnel (e.g., Emergency Operations Center, Fire Chief,</p>	V 416			

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V 416	Continued From page 11 Emergency, Medical Services). The CSS was unable to produce documentation that reflected collaboration with the local disaster management agency, nor did he/she have personal knowledge that the facility had communicated with the agency.	V 416			
V 544	494.90(a)(1) POC-ACHIEVE ADEQUATE CLEARANCE Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis. This STANDARD is not met as evidenced by: Based on observation, staff interview, clinical record and administrative document review, the facility failed to implement the adequacy of dialysis plan of care for 1 of 9 sampled patients (Patient 9) when Patient 9 was dialyzed with a Dialysate Flow Rate (DFR) lower than ordered by the physician. This failure had the potential to increase the risk of patients not meeting patient care objectives regarding adequacy of dialysis. Findings: On 2/24/11 at 8:35 a.m., Patient 9's dialysis was initiated by CHT1. The DFR was set at 600 ml/minute. During additional observations at 9:25 a.m. and 12 p.m., Patient 9's treatment continued with a DFR of 600 ml/minute. On 2/24/11 at 12 p.m., during an interview, CHT1 acknowledged Patient 9's DFR was set at 600 ml/minute, and the doctor's order called for the	V 544		4/18/11	

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V 544	Continued From page 12 DFR to be set at 800 ml/minute. A review of Patient 9's dialysis flow sheet for 2/24/11 revealed a physician's order for the DFR to be set at 800 ml/minute. The facility's policy and procedure titled PRESCRIPTION VERIFICATION AND SAFETY CHECKS (Procedure: 1-03-02, Last revised 9/10) was reviewed. Item 4 stipulated: "Verify on patient electronic treatment record the following prior to every dialysis treatment . . . dialysate flow" and "Patient prescription is verified by teammate prior to initiation of treatment."	V 544			
V 726	494.170 MR-COMPLETE, ACCURATE, ACCESSIBLE The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility. This STANDARD is not met as evidenced by: Based on staff interview, clinical record and administrative document review, the facility failed to maintain accurate medical records for 1 of 9 sampled patients (Patient 1) when: 1. Patient 1's physician's orders did not reflect the dialyzer (device that serves as an artificial kidney during dialysis) being used; 2. Patient 1's dialysis treatment (the process of filtering blood for harmful waste products while using an artificial kidney connected to a machine) record did not accurately reflect or explain changes in the treatment.	V 726		4/18/11	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552504	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 02/25/2011
NAME OF PROVIDER OR SUPPLIER TOKAY DIALYSIS CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 312 SOUTH FAIRMONT AVENUE, SUITE A LODI, CA 95240		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
V 726	<p>Continued From page 13</p> <p>These failures had the potential to increase patient risk of not meeting patient objectives for adequacy of dialysis treatment.</p> <p>Findings:</p> <p>On 2/23/11 review of the medical record revealed Patient 1 was admitted to the facility for dialysis treatment on 1/27/11.</p> <p>A review of Patient 1's medical record revealed physician's orders that directed staff to use use a Revaclear dialyzer (brand of non-reuse dialyzer) for Patient 1's dialysis treatments. On 2/5/11, the physician's order was changed to a Polyflux 24 R dialyzer (brand of re-use dialyzer). On 2/22/11, the Physician's order was to change back to a Revaclear non-reuse dialyzer was entered in the electronic record by RN1.</p> <p>Review of Patient 1's "Post Treatment" forms for 2/5/11 and 2/8/11 revealed "Polyflux 24 R" (reuse dialyzer) appeared in the PRESCRIPTION INFORMATION portion of the records. In the MACHINE SETUP portion of the records, the signatures of the two staff members who checked the reuse dialyzer for disinfectant presence and/or residual disinfectant were completed.</p> <p>Review of the "Post Treatment" forms for 2/10/11 through 2/19/11 revealed "Polyflux 24 R" (reuse dialyzer) appeared in the PRESCRIPTION INFORMATION portion of the records. However, in the MACHINE SETUP portion of the records, the words "Non-reuse" appeared on the signature lines for the disinfectant checks. The patient's order was for a Polyflux 24 R as a "reuse dialyzer."</p>	V 726			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552504	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 02/25/2011
NAME OF PROVIDER OR SUPPLIER TOKAY DIALYSIS CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 312 SOUTH FAIRMONT AVENUE, SUITE A LODI, CA 95240		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
V 726	Continued From page 14 A facility procedure titled PRESCRIPTION VERIFICATION AND SAFETY CHECKS (Procedure: 1-03-02, Last revised September 2010) was reviewed. The procedure stipulated: Item 1: "Trained teammates will verify the dialysis prescription . . . prior to each treatment initiation," and Item 4: "Verify on patient electronic treatment record the following prior to every dialysis treatment. Prescribed: Dialyzer . . ." In a 2/24/11 at 4 p.m. interview, the ADM (alternate) confirmed that the Revaclear dialyzer, a "Non-reuse" dialyzer, was used from 2/10/11 through 2/19/11 because the words "Non-reuse" were entered in the spaces for the staff to sign for the presence and/or the absence of residual disinfectant in the dialyzer. In an 2/23/11 at 4:30 p.m. interview, RN1 stated she had spoken to a colleague who had obtained a verbal physician's order for Patient 1 to use a Revaclear dialyzer. RN1 stated Patient 1 had been using the Revaclear dialyzer per the verbal order. RN1 stated she corrected the order so that the Revaclear appeared in the PRESCRIPTION INFORMATION portion of the treatment record from 2/22/11 and forward.	V 726			