

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

PRINTED: 10/29/2009
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 552584	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 07/09/2009
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE OF MID-WILSHIRE			STREET ADDRESS, CITY, STATE, ZIP CODE 3545 WILSHIRE BOULEVARD, SUITE #103 LOS ANGELES, CA 90010	
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V 000	INITIAL COMMENTS Surveyor: 11683 The following reflects the findings of Department of Public Health during a Recertification Survey. Representing the Department of Public Health: Rosalinda Ramos, RN, HFEN Sylvia Villaflores, REHS, HFE I	V 000		
V 116	494.30(a)(1)(i) CDC RR-5 AS ADOPTED BY REFERENCE Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient. -- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient. -- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients. This STANDARD is not met as evidenced by: Surveyor: 11683 Based on observation and interview, the facility failed to ensure that items, such as adhesive tape, taken into the dialysis station used for a patient should not be taken back to the common storage area for use of other patients and should not kept in the pocket of the staff's gown. Finding:	V 116		

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 116	Continued From page 1 1. On July 6, 2009, at approximately 8:20 a.m., during the tour of the treatment area, RN 2 was observed changing Patient 1's catheter dressing on the right chest. The licensed staff took pieces of tapes from a roll of adhesive tape that was by the arm chair and then placed it back in a cart that was mixed with other clean supplies. 2. On July 6, 2009, at approximately 9:15 a.m., during a treatment observation, PCT 1 was preparing Patient 3 to be taken off from the hemodialysis machine. The PCT took a roll of tape from his pocket, cut pieces from the roll of tape, and hang them on the side of the armchair. The pieces of tapes were used on Patient 3's access site located on the left arm. At 10 a.m., in an interview with PCT 1, he stated he was not aware that he should not keep rolls of tapes in his gown's pocket.	V 116			
V 126	494.30(a)(1)(i) CDC RR-5 AS ADOPTED BY REFERENCE Hepatitis B Vaccination Vaccinate all susceptible patients and staff members against hepatitis B. This STANDARD is not met as evidenced by: Surveyor: 11683 Based on record review and staff interview, the facility failed to ensure that there was a documentation in the employee health files to indicate that hepatitis B vaccination was offered to the facility staff members. Findings: On July 9, 2009, at approximately 8 a.m., four	V 126			

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V 126	Continued From page 2 employee health files (three (3) registered nurses and a registered dietitian) were reviewed. Three (3) of the four (4) employee health files did not have written evidence to indicate that the hepatitis B vaccine was offered to the employees at the time of their hire and thereafter. At approximately 9:30 a.m., in an interview with RN 4, she stated that she was aware that the vaccine was offered to all the staff members, however, she stated there was no evidence in the employee health files.	V 126			
V 143	494.30(b)(2) OVERSIGHT [The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and This STANDARD is not met as evidenced by: Surveyor: 11683 Based on observation, interview, and record review, the facility failed to ensure that there were no expired, extra and unlisted medications available for use. Findings: On July 6, 2009, at 11 a.m., during the medication storage observation with administrative staff, the following were noted: 1. In the medication refrigeration: a. There was a heavy accumulation of ice in the freezer. b. There were multi-doseopened and undated	V 143			

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V 143	<p>Continued From page 3</p> <p>vials of Epogen and a bottle of Heparin Sodium.</p> <p>c. There was a bottle of Tuberculin Purified Protein Derivative, which was opened on March 8, 2009. A review of the Manufacturer's handout stipulated that vials in use more than days should be discarded due to possible oxidation and degradation, which may affect potency.</p> <p>2. In the emergency cart:</p> <p>a. The following listed medications/supplies were not available such as 4 vials of Calcium Chloride, 2 vials of Sterile Water, 10 pieces of 21 G Needle, 2 rolls of paper tape, 2 rolls of plastic tape, 1 piece of Tourniquet and a Stop watch.</p> <p>b. There were extra medications/supplies which were listed such as 8 vials of 50% Dextrose, 23 vials of Diphenhydramine 50mg/ml and 23 ampules of Epinephrine 1:1000.</p> <p>c. There were expired medications/supplies such as 20 packets of Povidone Iodine Pad with expiration date of May 2009 and 4 packs of Povidone Iodine Swab with expiration date of April 2009.</p> <p>d. There were medications that were not listed such as 10 vials of Epinephrine 1:10,000.</p> <p>At 1 p.m., during an interview with RN 1, while reviewing the Crash Cart Equipment and Supply Log, she stated that she checked to make sure the emergency cart was checked for completeness, accuracy and expired medications/supplies.</p> <p>3. There were 2 boxes of glucometer control solution with expiration date of April 21, 2009.</p>	V 143			

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V 243	<p>494.40(a) ANSI/AAMI RD52:2004 AS ADOPTED BY REFERENCE</p> <p>6.5 Concentrate distribution: bicarb jugs rinsed daily/stored dry Bicarbonate concentrate jugs should be rinsed with treated water and stored inverted at the end of each treatment day. Pick-up tubes should also be rinsed with treated water and allowed to air dry at the end of each treatment day.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 15727 Based on observation and interview, the facility failed to store the bicarbonate jugs inverted.</p> <p>Findings:</p> <p>During a tour of the storage room on July 6, 2009, at 7:30 a.m., approximately 14 empty bicarbonate jugs were stored horizontally with covers in place.</p> <p>During an interview on July 6, 2009, at 10:10 a.m., Chief Technician A stated there was water in the containers.</p> <p>During an interview on July 9, 2009, at 2:30 p.m., Chief Technician B stated the bicarbonate jugs should have been inverted to allow air dry.</p>	V 243			
V 401	<p>494.60 PHYSICAL ENVIRONMENT</p> <p>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>This STANDARD is not met as evidenced by: Surveyor: 11683</p>	V 401			

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V 401	Continued From page 5 Based on observation and interview, the facility failed to maintain a safe environment for patients, staff, and public during hemodialysis treatment. Findings: On July 6, 2009, at approximately 7:35 a.m., during the initial tour of the facility, it was observed that medications such as Epogen, Zemplar, Heparin and syringes were left unattended on an area beside the sink. At 10 a.m., in an interview with RN 2, she stated that she was preparing the medication and had to leave areas to attend to a patient's need. She further stated that it would not happen again.	V 401			
V 411	494.60(d)(1) EMERGENCY PREPAREDNESS [Staff training must be provided and evaluated at least annually and include the following:] (iii) Ensuring that nursing staff are properly trained in the use of emergency equipment and emergency drugs. This STANDARD is not met as evidenced by: Surveyor: 11683 Based on observation, interview and record review, the facility failed to ensure that nursing staff members were trained in the use of the facility's suction machine. Findings: On July 6, 2009, at approximately 12:15 p.m., an emergency equipment, a suction machine was checked to see if it was functional. During the demonstration of RN 1 regarding the use of the suction machine for a patient, the employee was	V 411			

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V 411	Continued From page 6 unable to make the suction machine work. The other Registered Nurses were requested, however, they were unable to make it work as well. At 1 p.m., in an interview with RN 1, she stated that she could not remember having had an in-service and/or return demonstration on the use of the suction machine.	V 411			
V 454	Review of the in-service record log failed to show documentation to indicate training on the use of suction machine was done for the licensed staff members of the facility. 494.70(a)(3) PATIENTS' RIGHTS [The patient has the right to-] (3) Privacy and confidentiality in all aspects of treatment; This STANDARD is not met as evidenced by: Surveyor: 11683 Based on observation, interview, and record review, the facility failed to ensure that Patient 2 was provided privacy during the hemodialysis treatment. Findings: On July 6, 2009, at approximately 8:30 a.m., Patient 2 was observed asleep while receiving hemodialysis treatment and was wearing green colored underwear which was exposed and was in view to other patients, staff and visitors. The patient's access site was located on his left upper thigh. At 10:30 a.m., Patient 2's hemodialysis treatment was completed. The patient got up from the chair and wearing his green underwear in front which was exposed for public view to other	V 454			

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V 454	Continued From page 7 patients, staff and visitors. The patient continued to get dressed while Certified Hemodialysis Technician (CHT) 1 was disconnecting the tubing from the hemodialysis machine. An interview with the CHT 1, he stated the patient had always dressing and undressing by the chair without providing for the use of a privacy curtain.	V 454		
V 502	494.80(a)(1) ASSESSMENT CRITERIA 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: Surveyor: 15727 Based on interview and record review, the facility failed to include the evaluation of the current health status of Patient 4. Findings: A review of the comprehensive assessment for Patient 4 revealed there was no documentation of the patient's current health status. The section of the comprehensive interdisciplinary assessment for team evaluation of stability status was not checked out. During an interview on July 9, 2009, at 10:25 a.m., the clinical manager stated the current health status to indicate stable or unstable should be documented in the initial comprehensive assessment.	V 502		
V 503	494.80(a)(2) ASSESSMENT CRITERIA	V 503		

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V 503	<p>Continued From page 8</p> <p>[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,</p> <p>This STANDARD is not met as evidenced by: Surveyor: 11683 Based on observation, interview, and record review, the facility staff failed to follow physician's order for blood/dialysate flow rates for Patients 1 and 2.</p> <p>Findings:</p> <p>1. On July 6, 2009, at approximately 8:15 a.m., Patient 1 was observed receiving hemodialysis treatment via right subclavian catheter. The patient was dialyzing on a 3 potassium (K) and 2.5 calcium bath. The blood flow rate (BFR) was 350 and dialysate flow rate (DFR) was 800.</p> <p>A review of daily treatment record from June 22, 2009 through July 6, 2009, revealed the BFR was from 201 to 298 and DFR was 800. A review of the physician's order dated May 18, 2009, indicated the BFR was 300 and DFR was 800.</p> <p>2. On July 6, 2009, at approximately 830 a.m., Patient 2 was observed receiving hemodialysis treatment via a fistula located on the left upper thigh. The patient was dialyzing on a 1 potassium (K) and 2.5 calcium bath. The blood flow rate (BFR) was 400 and dialysate flow rate (DFR) was 800.</p>	V 503			

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V 503	Continued From page 9 A review of the daily treatment record dated May 22, 2009 through July 1, 2009, revealed the BFR was from 237 to 397 and DFR was 400. A review of the physician's order dated May 6, 2009, indicated the BFR was 400 and DFR was 800. In an interview, on July 8, 2009, at 10 a.m., while reviewing the clinical record, RN 4 stated that the physician's order for the BFR should have been followed.	V 503			
V 504	494.80(a)(2) ASSESSMENT CRITERIA [The patient's comprehensive assessment must include, but is not limited to, the following:] Blood pressure, and fluid management needs. This STANDARD is not met as evidenced by: Surveyor: 11683 Based on record review and interview, the facility staff failed to ensure that the comprehensive assessment included a blood pressure and fluid management needs for Patient 1. Findings: A review of the daily treatment record dated July 1, 2009, for Patient 1 revealed that on July 1, 2009, at 8:30 a.m., documented the blood pressure (B/P) reading was 96/45. The patient was resting comfortably and denied any complaints. At 9:05 a.m., the patient's blood pressure reading was 96/45. The patient denied any complaints and was resting comfortably. At 10:09 a.m., the patient's blood pressure reading was 96/45. The patient denied any complaints and was resting comfortably. The	V 504			

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V 504	Continued From page 10 patient was administered 150 cc of normal saline solution for B/P support. Further review of the Hemodialysis Record on the above dates failed to show documentation that the patient's episodes of low blood pressure with administration of normal saline was further assessed by the licensed nurse. On July 8, 2009, at 10 a.m., in an interview with RN 4, while reviewing the clinical record, she stated that there was no documented evidence to indicate why the patient was not administered normal saline on two other occasions on the same day when the B/P reading was the same. A review of the physician's order dated May 18, 2009, indicated an order for normal saline 0.9% to maximum of 1000 cc as needed for hypotension or cramping. The physician order did not have parameters as to how much amount of fluid to be infused per hour and for how long it should be infused.	V 504			
V 506	494.80(a)(3) ASSESSMENT CRITERIA [The patient's comprehensive assessment must include, but is not limited to, the following:] Immunization history, and medication history. This STANDARD is not met as evidenced by: Surveyor: 15727 Based on interview and record review, the facility failed to provide the immunization history of Patients 1, 2, and 4. Findings:	V 506			

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V 506	Continued From page 11 1. A review of Patient 4's medical record revealed no documentation of the patient's immunization history. During an interview on July 8, 2009, at 10:30 a.m., the clinical manger stated the immunization record should be completed. Surveyor: 11683 2. A review of Patient 1's medical record revealed that he was admitted to the facility on April 24, 2009, with diagnoses of diabetes mellitus type II and end stage renal dialysis. Further review of the clinical record failed to show documentation of Patient 1's immunization history. 3. A review of Patient 2's medical record revealed that he was admitted to the facility on May 16, 2008, with diagnoses of end stage renal disease and hypertension with renal failure. The medical record failed to show documentation of Patient 2's immunization history.	V 506			
V 517	494.80(b)(2) FREQUENCY OF ASSESSMENT A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in §494.90. This STANDARD is not met as evidenced by: Surveyor: 15727 Based on interview and record review, the facility failed to do a follow up comprehensive reassessment within 3 months after the completion of the initial assessment for Patient 4. Findings:	V 517			

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V 517	Continued From page 12 A review of Patient 4's medical record revealed no documentation of a 90 day follow up comprehensive reassessment.	V 517			
V 520	During an interview on July 8, 2009, at 9:35 a.m., the clinical manager stated a comprehensive reassessment should have been done. 494.80(d)(2) PATIENT REASSESSMENT [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-] (2) 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. This STANDARD is not met as evidenced by: Surveyor: 15727 Based on interview and record review, the facility failed to do a monthly comprehensive reassessment for Patient 4. Findings: A review of Patient 4's medical record revealed an albumin levels of 4.4 on 5/6/09 and 3.2 on 6/7/09. There was no documentation in the	V 520			

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V 520	Continued From page 13 medical record that the nutritional status of the patient was addressed by the registered dietician. The patient's hemoglobin levels were 8.7 on 6/17/09 and 8.8 om 7/1/09. There was no documentation in the medical record that the anemia was addressed. During an interview on July 8, 2009, at 1:42 p.m., the registered dietician stated the patient stopped eating red meat and that was the reason the low albumin level. However, there was no documentation in the medical record that the low albumin levels were addressed. There was no documentation that the interdisciplinary team had done a monthly reassessment of the patient's status.	V 520		
V 541	494.90 PATIENT PLAN OF CARE 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. This STANDARD is not met as evidenced by: Surveyor: 15727 Based on interview and record review, the facility failed to develop a care plan for Patients 1 and 4.	V 541		

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V 541	Continued From page 14 Findings: 1. On July 8, 2009, a review of the medical record revealed Patient 4 was admitted to the facility on April 1, 2009. There was no documentation of a comprehensive care plan developed by the interdisciplinary team. Three months and 1 week had passed since admission and there was no documentation of a care plan developed for Patient 4 At the same time during an interview, the clinical manager stated a care plan should have been developed within 15 days of the initial comprehensive assessment. Surveyor: 11683 2. Patient 1 was admitted to the facility on April 24, 2009, with diagnoses of end stage renal disease and diabetes mellitus type 2. The patient currently residing in a skilled nursing facility. Further review of the medical record failed to show documentation to indicate that a comprehensive care plan was developed by the interdisciplinary team for the patient. On July 8, 2009, at 10 a.m., in an interview, while reviewing the clinical record, RN 4 concurred that there was no comprehensive care plan developed for the patient.	V 541			
V 676	494.130 LABORATORY SERVICES The dialysis facility must provide or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. Any laboratory	V 676			

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V 676	Continued From page 15 services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter. This STANDARD is not met as evidenced by: Surveyor: 15727 Based on interview and record review, the failed to obtain blood cultures ordered by the physician for Patient 4. Findings: A review of Patient 4's medical record revealed a physician's order June 8, 2009, for blood culture and sensitivity times 2. The order was carried out. However, a review of the section of the medical record for laboratory results revealed no results for blood cultures in June, 2009. During an interview on July 8, 2009, at 1 p.m., the clinical manger could not explain why the blood cultures were not done.	V 676			
V 681	494.140 PERSONNEL QUALIFICATIONS All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions.	V 681			

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V 681	Continued From page 16 This STANDARD is not met as evidenced by: Surveyor: 11683 Based on record review and staff interview, the facility failed to ensure that the dialysis staff met the personnel qualifications and demonstrated competencies necessary to meet the comprehensive needs of the patients. Findings: On July 9, 2009, at approximately 8 a.m., four (4) personnel files of the dialysis staff members were reviewed and revealed the following: Registered Nurse (RN) 1 was hired on February 13, 2009, as a hemodialysis staff nurse. There was no documentation of a competency evaluation, an infection control training and a tuberculosis evaluation prior to the employee starting to work. RN 2 was hired on November 11, 2007, as Nursing Service Coordinator and took a new role of hemodialysis team leader on March 9, 2009. There was no documentation of an orientation and a tuberculosis evaluation prior to starting to work. RN 4 was hired on February 15, 2008, as Interim Clinical Manager. There was no written documentation of a tuberculosis evaluation prior to starting to work. Registered Dietitian (RD) was hired on October 8, 2008. The license/and/or certificate had expired on May 31, 2009. At approximately 10 a.m., interview with RN 4, she stated that hepatitis and tuberculosis testings were the required test for the staff members prior to starting to work. The facility's policy on New	V 681		

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V 681	Continued From page 17 Hire Medical Evaluation was reviewed. It stipulated that all new Direct Patient Care and Indirect Patient employees were required to have various health requirements (such Hepatitis and Tuberculosis testing) completed after an offer of employment was extended. The results must be received and evaluated before an employee actually starts working.	V 681			
V 715	494.150(c)(2)(i) POLICIES AND PROCEDURES The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; This STANDARD is not met as evidenced by: Surveyor: 11683 Based on observation, interview and record review, the facility staff failed to ensure the facility's policy on Termination of Treatment was followed for Patient 9. Findings: On July 6, 2009, at approximately 10:30 a.m., Patient 9 was observed receiving hemodialysis treatment via the right femoral catheter. In an interview with the patient, she stated that her blood lines were still red in color and the PCT terminated the treatment. She further stated that her blood was not completely returned during a hemodialysis treatment. In an interview with RN 1, she stated that the blood lines should be pink in color to start the	V 715			

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V 715	Continued From page 18 rinse and apparently the blood lines at this time was still red in color.	V 715			
V 727	494.170(a) PROTECTION OF THE PATIENT'S RECORD The dialysis facility must- (1)Safeguard patient records against loss, destruction, or unauthorized use; and (2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following: (i) The transfer of the patient to another facility. (ii) Certain exceptions provided for in the law. (iii) Provisions allowed under third party payment contracts. (iv) Approval by the patient. (v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program. This STANDARD is not met as evidenced by: Surveyor: 11683 Based on observation and interview, the facility failed to safeguard patients' records against unauthorized use. Findings: On July 6, 2009, at 7:35 a.m. during the initial tour of the facility, the following was observed:	V 727			

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V 727	<p>Continued From page 19</p> <ol style="list-style-type: none"> 1. A tray of papers with patients' information such as the name, account numbers were left unattended beside the fax machine. The fax machine was located on a busy hallway for patients, staff and visitors. The records were accessible to any patients, staff and visitors as they passed through the hallway to get into each hemodialysis station. On July 9, 2009, at 9 a.m., the records were presented to RN 3 and he stated that they'll make sure that the records would be collected and filed away as soon as it was received. 2. A box full of patient records including comprehensive initial assessments were found under the sink by the nurses station. 3. Blood draw kits consisting of blood tubes and a sheet of paper with patient's name, account name, date of birth, name of the physician and other information lying on top of the dirty sink, which was accessible to patients, staff and visitors as they pass by. <p>Surveyor: 15727</p> <ol style="list-style-type: none"> 4. During an observation on July 9, 2009 at 10:30 a.m., in the conference room, there was patient information and radiology reports left on top of the shelf above the fax machine. <p>At the same time during an interview, the clinical manager stated the documents should not have been left on the shelf in the conference room. She further stated that the janitorial service had</p>	V 727			

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V 727	Continued From page 20 access to the room for cleaning after office hours.	V 727			