STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	552600	A. BUILDING ______ B. WING ______	11/18/2010

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WELLBOUND OF SAN LEANDRO	**1040 DAVIS STREET, SUITE 101 SAN LEANDRO, CA 94577**

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V 000	INITIAL COMMENTS	V 000		

V 000 INITIAL COMMENTS

The following reflects the findings of the California Department of Public Health during a recertification survey conducted from 11/15/10 to 11/17/10.

Representing the Department of Public health: Dorothy Rice, HFEN; Lutgarda Sturms, HFEN; Nikki Kratt, HFEN; Elida Huerta, HFEN; Helen Ho, HFEN; and Karen Riley, HFEN.

The census at the start of the survey was 36 (32 Peritoneal Dialysis, and 4 Home Hemodialysis patients).

Acronyms and Abbreviations commonly used in this report:
AVF arteriovenous fistula
AVG arteriovenous graft
BP blood pressure
BUN blood urea nitrogen
CAPD continuos ambulatory peritoneal dialysis
CCPD continuous cycling peritoneal dialysis
DI deionization
DM diabetes mellitus
EPO epogen, erythropoietin
ESRD end stage renal disease
HD hemodialysis
HHD home hemodialysis dialysis
Kt/v kinetic modeling for dialysis adequacy reflecting
clearance, time and volume
MR medical record
MA medical assistant
P&P policies and procedures
PPE personal protective equipment
PD peritoneal dialysis
QAPI quality assurance program improvement
RN registered nurse

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 000	Continued From page 1 UF ultrafiltration UFR ultrafiltration	V 000		
V 128	494.30(a)(1)(i) IC-HBV-ISOLATION (EXISTING FACILITY) Isolation of HBV+ Patients To isolate HBsAg positive patients, designate a separate room for their treatment. For existing units in which a separate room is not possible, HBsAg positive patients should be separated from HBsAg susceptible patients in an area removed from the mainstream of activity. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to provide a dedicated isolation room for one hemodialysis patient (Patient 2), who tested positive for Hepatitis B, of six patients reviewed. Failure to do so, increased the risk of cross contamination from blood borne pathogens for the staffs and the other patients who received care in the same room. Findings: On 11/15/10, during a record review, Patient 2's laboratory report, dated 9/9/10 and 10/8/10, showed Patient 2 had a positive Hepatitis B surface antigen (HbsAg) blood test. A positive HbsAg was an indication that the patient was a carrier of the Hepatitis B virus. Further review of the medical record indicated that Patient 2 started his training on 9/9/10 and finished his training on 11/1/10. Patient 2 's training was done in Training Room 3 which according to the Clinical Manager (CM1) and the	V 128		12/2/10

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V 128	Continued From page 2	V 128		

Regional Director of Operations (RDO), was not dedicated for Patient 2 during that time frame. Patient 2 came to the facility on MWF (Monday, Wednesday and Friday) schedule. During interview on 11/17/10, CM1 said that on the days Patient 2 was not in, Training Room 3 was used by other patients for their clinical monthly visit. "Patient 2's machine was ordered for him and he took the machine home after his training but the machine was in room 3 while the patient was getting trained", CM1 said. She further said that the room was "terminally cleaned" at the end of the day.

During an interview on 11/17/10, RDO said that usually, Patient 2 received his treatment at the end of the day. Review on 11/17/10 of the facility policy and procedure for "Isolation", dated 11/08/09, showed, " Schedule HBV+ patient center visits as the last patient of the day in the room (i.e., do not utilize the room for other patients after the hepatitis B patient has used the room)." Review of Patient 2's treatment records showed that the patient received treatments as early as 10 a.m. on some of his treatment days in order to accommodate his school schedule.

The nurses progress notes, dated 9/9/10 to 11/1/10 also indicated that Patient 2's fistula was difficult to cannulate requiring several attempts to stick the needle to get a good blood flow. This also posed an increased risk for blood spills and splatters while doing the needle manipulations.

According to the NIOSH (National Institute for Occupational Safety and Health) Health Hazard Evaluation Report No. 2000-0341-2839, provided for review by RDO, " HBV is resistant to drying, simple detergents and alcohol, and has been

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V 128	Continued From page 3 found to be stable on environmental surfaces for at least seven days. Thus, indirect inoculation can occur via inanimate objects (e.g., contaminated medical equipment or environmental surfaces)." According to the Center for Disease Control, HBV+ patients must dialyze in a separate isolation room during dialysis to prevent contact and transmission by contact with blood spills, splattering, or spurting of blood and other body fluids. "There was a letter dated 7/10/09 requesting for a waiver but to this date, has not received a response", according to the RDO on 11/17/10.	V 128		
V 142	494.30(b)(1) IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P The facility must- (1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit; This STANDARD is not met as evidenced by: Based on staff interview and record review, the facility failed to implement their policy and procedure for "Tuberculin Testing" for one (Patient 4) of five sampled patients. For Patient 4 the facility failed to have documentation in the medical record of the tuberculin test results prior to admission and also failed to perform an annual tuberculosis screening. This failure had the potential to put other dialysis patients and staff at risk for contracting tuberculosis. Findings: Review on 11/16/10 of the facility's policy and	V 142		1/31/11

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V 142	Continued From page 4 procedure "Tuberculin Testing", dated 2/24/10, showed that the purpose was "to test ... patients for exposure to and prevent transmission of tuberculosis". Review on 11/16/10 of Patient 4's "Patient Consent for Tuberculosis Skin Testing" showed (no date on document) only "3-18-09 Employer" for the section labeled for test date. There was no further information documented on the form. CM 1 (Clinical Manager) stated on 11/16/10 at 3:15 p.m. that Patient 4 had verbally informed the facility that he had a tuberculosis test done by his former employer and that it had been negative. There was no annual tuberculosis screening documentation found in the record. CM 1 also checked Patient 4's medical record and was not able to find the information.	V 142		
V 409	494.60(d)(1) PE-ER PREP STAFF-INITIAL/ANNUAL/INFORM PTS The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following: (i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of- (A) What to do; (B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated; (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	V 409		12/15/10

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V 409	Continued From page 5 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 (D) How to disconnect themselves from the dialysis machine if an emergency occurs. This STANDARD is not met as evidenced by: Based on interview and document review, the facility failed to provide annual staff training in emergency preparedness. This failure could potentially jeopardize the safety of patients during an emergency. Findings: On 11/16/10, review of the personal files showed none of the six employees reviewed had evidence of annual emergency /disaster training. Review of on-line training classes for the employees showed only fire safety training. Review of the content of the fire safety training indicated the focus was to understand how to use a fire extinguisher. The medical assistant (MA) was interviewed on 11/16/10 at 2:18 p.m. She was asked to locate evidence of annual staff disaster/emergency training but could not. She stated, "We did the California Shakeout", an earthquake drill held the prior month. The RN was interviewed on 11/17/10 at 9:30 a.m. He was asked when he last participated in emergency/disaster training. He stated, "We did the Earthquake California" (The great California Shakeout held throughout the State on 10/21/10 at 10:21 a.m.). He was asked what other disaster/emergency drills he participated in. He	V 409		

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V 409	Continued From page 6 had no answer. During an interview with clinical managers CM 1 and CM 2 on 11/17/10 at 10:05 a.m., they looked online at the courses staff were expected to complete yearly and could not find any course that provided disaster/emergency training. CM 1 acknowledged as well that fire drills were to be conducted quarterly. She stated since she delegated the coordination of disaster drills, it will be put on the calendar to be conducted on the first working day of each quarter. She stated "We started last month with the Great California Shake Out." Review of "Fire Safety and Diaster Plan" indicated the facility will have a "Fire and Diaster Plan to follow in the event that a fire, suspected fire, or disaster would occur in the facility." "The purpose of a safety plan is to ensure that all employees and patients are made aware of this plan via education and drills so that evacuation, if necessary, can be conducted with calm and orderly precision." According to the policy, fire drills were to be conducted quarterly. Review of the disaster drill log indicated the only fire drill was documented on 5/28/08.	V 409		
V 586	494.100(b)(1) H-PT/CAREGIVER DEMO COMPREHEND TRAINING The dialysis facility must - (1) Document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training; This STANDARD is not met as evidenced by: Based on interview and record and document review, the facility failed to provide evidence that	V 586		12/31/10

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V 586	Continued From page 7	V 586		

one (Patient 4) of five sampled patients received comprehensive home dialysis training and demonstrated competence. This failure potentially affected Patient 4's ability to perform home dialysis adequately and safely.

Findings:

Review of Patient 4's clinical record on 11/16/10 showed he was admitted to the facility on 3/19/09. He was to receive training so he could perform peritoneal dialysis at home. Review of the record showed no documentation that the Peritoneal Training Checklist had been completed.

Review of the facility's "Patient Training Guidelines", dated 07/02/08, indicated, "Standardized training materials will be utilized and supplemented as needed." According to the Guidelines, the purpose was to, "ensure consistent and individualized training for patients and caregivers, to safely dialyze at home." Twenty-two different topics listed on the Peritoneal Training Checklist were to be discussed and any associated procedures demonstrated.

According to the policy, the training instructor was to, "Use the training checklist to indicate the dates of the discussions of each topic, the demonstrations given, and the successful completion of return demonstrations. Completion of the checklist is a requirement before the formal training is finished. Evaluate all learning by written and/or verbal tests as well as return demonstrations. Following the completion of the training, give the patient a certificate and schedule them for a follow-up office visit within two weeks."

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V 586	Continued From page 8 Review of Patient 4's clinical record showed a Certificate of Completion dated 5/19/09 had been issued for Patient 4. Review of the Home Visit Data Summary Report, dated 5/19/09 indicated CM 1 documented that Patient 4 demonstrated proper procedure for performing home dialysis. The clinical manager (CM 1) was interviewed on 11/17/10 at 10:10 a.m. She confirmed she was Patient 4's training instructor and confirmed Patient 4's clinical record did not contain the Peritoneal Training Checklist. CM 1 reviewed a number of documented Clinical Visit Logs (visit notes) she generated when Patient 4 came in for training. She agreed the content of the visit notes did not ensure all topics listed on the Peritoneal Training Checklist were reviewed as required with Patient 4. CM1 stated Patient 4 "probably didn't read the entire (training) manual and was still referring to his "cheat sheet" . She stated Patient 4 did not do the 12 self-tests and she was unable to verify that she discussed the content of each self-test with him to assure he understood the material. She stated, "I thought he was ready (on 5/19/09 when his certificate was issued and the home visit done to ensure complete independence in performing peritoneal dialysis). I don't know why he came back for more training." Review of the Clinical Visit Log dated 5/28/09 indicated, "Pt brought in cycler log sheets which indicated high neg. UF. (Patient 4 was not pulling enough fluid off during his dialysis) Pt instructed to use 2.5% Dex and to place cycler in a position closer to bed height. (During home visit cycler was noted to be approx.(imately) 15 inches above	V 586		

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V 586	Continued From page 9 the bed level.)"	V 586		
V 587	494.100(b)(2),(3) H-FAC RECEIVE/REVIEW PT RECORDS Q 2 MONTHS The dialysis facility must - (2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and (3) Maintain this information in the patient ' s medical record. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to retrieve, review, and maintain the self-monitoring data required of all its home dialysis patients, when the medical record of one of five sampled patients (Patient 5) did not contain any completed flow sheets. This failure could result in the facility staff's inability to accurately interpret treatment outcomes, and to thoroughly monitor the patient's compliance with his treatment plan. Findings: Patient 5 initially began receiving hemodialysis (the removal of waste products from the body by pumping blood through the semi-permeable membrane of an artificial kidney) at an acute care hospital (ACH1) on 10/19/07. Soon after, he was trained to do home dialysis, specifically CAPD (continuous ambulatory peritoneal dialysis -- the manual infusion of dialysate [a special fluid] by gravity through a catheter into the abdominal cavity, where it sits and absorbs waste products across the peritoneum [in this case, the semi-permeable membrane] and is then drained and replaced with fresh dialysate several times).	V 587		12/16/10

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V 587	Continued From page 10 On 9/16/09, Patient 5 transferred to his first home dialysis facility (HDF1) where he continued with home dialysis until 8/19/10, when he transferred to his current home dialysis facility (HDF2). During the medical record review on 11/15/10, the section labeled "Treatment Records" did not appear to contain any of Patient 5's completed flow sheets. Two Clinical Visit Reports, dated 5/28/10 and 7/12/10, contained documentation confirming Patient 5 did not bring his flow sheets with him. During an interview with the clinical manager on 11/16/10 at 10:30 a.m., when the missing flow sheets were requested, she stated, "The patient has never brought in his treatment records ...he always says he forgot them."	V 587		
V 681	494.140 PQ-STAFF LIC AS REQ/QUAL/DEMO COMPETENCY All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions. This STANDARD is not met as evidenced by: Based on staff interview, record and document review, the facility failed to ensure professional staff adhered to State statutes defining scope of	V 681		1/30/11

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V 681	Continued From page 11	V 681		

practice for registered dietitians. The registered dietitian wrote orders and received physician telephone orders for medications, potentially affecting the care of all 36 patients in the facility's census.

Findings:

According to the California Health and Safety Code Section 11150, "No person other than a physician, dentist, podiatrist, or veterinarian.............shall write or issue a prescription." Section 11150 contained no language describing prescriptive authority of registered dietitians, an unlicensed allied healthcare professional group in the State.

While reviewing Patient 1's clinical record on 11/15/10, the following facility document with Patient 1's name written on it was noted: "Physician's Standing Orders for the Renal Dietitian." According to the "Physician's Standing Orders for the Renal Dietitian", the "Policy" was: "Nephrologists (kidney specialists) authorize renal dietitians to initiate nutrition and nutrition-related interventions according to approved protocols." The "Procedure" was: "The renal dietitian may enter orders in the computer within the guidelines of the following standing orders. RD (registered dietitian) generated orders will be accepted and implemented. The MD will be notified of order changes and will sign the orders on the next update of the patient's dialysis orders." "Authorizations include: Nutritional Supplements/Malnutrition Protocol" specifying vitamin and mineral supplements; as well as phosphorus control, intravenous (IV) or oral Vit(amin) D or analogs (different forms) , and OCT (over the counter) fiber/stool softeners," all

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V 681	Continued From page 12 classified as drugs according to the California Business and Professions Code, Article 2 Section 4025 (a). During an interview with the renal dietitian on 11/15/10 at 1:45 p.m., she stated, "I manage bone, calcium, phosphorus, PTH unless there are doctors off protocol (physician has not agreed to the use of protocols), then I'll talk with them. Most of the MDs are on protocol." The renal dietitian stated she wrote orders for (phosphorus) binders, vitamin D, and Sensipar (a medication that lowers parathyroid hormone, phosphorus, and calcium levels). The renal dietitian stated she would take a telephone order (by the physician), "If I'm talking to the doctor about a med(ication) change." Review of the facility's overall policy entitled "Physicians Standing Orders/Protocols for the Renal Dietitian" indicated the policy was "Nephrologists authorize renal dietitians to initiate nutritional interventions according to approved standing orders." The procedure indicated, "Within accepted practice and state statues, the Renal Dietitian will either recommend or implement the following standing orders and protocols." Review of the Nutritional Supplements showed the renal dietitian could order "Renal Formulas (nutritional fluids)", "(vitamin) B complex plus (vitamin) C at DRI levels (dietary reference index) and Folic Acid (400 micrograms to 15 mg./day. The recommended dietary allowance for folic acid, a B vitamin, is 400 micrograms daily. Fifteen mg. a day is 38.5 times the recommended daily dose." The procedure did not outline how the renal dietitian would "choose" the amount of folic acid to order. The renal dietitian could order the	V 681		

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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
V 681	Continued From page 13 following oral preparations of minerals: "Calcium", "Zinc per (corporate) zinc treatment parameters", and "Oral Iron per (corporate) iron treatment parameters." Review of the Zinc treatment parameters indicated the renal dietitian was required to recognize zinc deficiency symptoms and proceed to a decision tree to initiate appropriate zinc supplement therapy. The renal dietitian would be required to recognize and evaluate any adverse symptoms to guide further therapy. On 11/17/10 at 11:07 a.m., the renal dietitian restated her role in generating orders. She stated she would enter her recommendations into the computer and the physician would sign off (either by the physician's order computer program or by fax) and then the order would be implemented. Review of a Home Hemodialysis Change Order Report for Patient 1 showed an order generated on 9/9/10 by the renal dietitian increasing the dose of Renvela, a medication that binds with phosphorus to decrease absorption of phosphorus. The renal dietitian was listed as entering the order and noting the order on 9/9/10. The order was to start on 9/9/10, the date the renal dietitian entered the order. A fax date imprinted on the top of the order showed the order was not faxed from the facility until 10/12/10 and the physician did not sign the order until 10/14/10. On 11/17/10, the renal dietitian produced correspondence from the California Dietetic Association to the Department of Public Health dated 4/8/08, asking 1. whether registered dietitians could accept and transmit "a verbal or electronically submitted order from the referring	V 681		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	552600	A. BUILDING ______ B. WING ______	11/18/2010

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V 681	Continued From page 14 physician for medical nutrition therapy consistent with an established protocol (pre-approved by the physician and the governing bodies of the medical institution." 2. whether there were "any situation legally in which the RD may not accept and transmit a verbal or electronically submitted order from the referring physician for medical nutrition therapy consistent with an established protocol?" The Department of Public Health responded: "In licensed health facilities which (the Department) regulates, the RD can accept and transmit verbal or electronically submitted orders as long as it is consistent with an established and approved protocol to implement medical nutrition therapy. This authority under Business and Professions Code section 2586 (b) does not include modifying physician's orders for drugs or medication."	V 681		
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 interview and record review, the facility failed to maintain complete and accurate records on all its home dialysis patients, when the medical records of two of five sampled patients (Patients 5 and 2) and one non-sampled patient (Patient 6) did not contain the training records. This failure would prevent confirmation of the training and what it specifically included, resulting in	V 726		12/31/10

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V 726	Continued From page 15 assumptions by the staff and possible treatment errors by the patient. Findings: 1. Record review on 11/15/10 showed Patient 5 initially began receiving hemodialysis (the removal of waste products from the body by pumping blood through the semi-permeable membrane of an artificial kidney) at an acute care hospital (ACH1) on 10/19/07. Soon after, he was trained to do home dialysis, specifically CAPD (continuous ambulatory peritoneal dialysis -- the manual infusion of dialysate [a special fluid] by gravity through a catheter into the abdominal cavity, where it sits and absorbs waste products across the peritoneum [in this case, the semi-permeable membrane] and is then drained and replaced with fresh dialysate several times). On 9/16/09, Patient 5 transferred to his first home dialysis facility (HDF1) where he continued with home dialysis until 8/19/10, when he transferred to his current home dialysis facility (HDF2). During Patient 5's medical record review on 11/15/10, no training records from ACH1 were noted. 2. Patient 6 completed training in CAPD at ACH1 on 1/5/05 and immediately started home dialysis. On 3/3/10, Patient 6 transferred to HDF2 and was trained in CCPD (continuous cyclic peritoneal dialysis - a treatment process similar to CAPD; however, the dialysate is instilled and removed by a machine during the night, enabling the patient to resume his usual day-time routine). On 11/16/10 at 11:00 a.m., when the clinical	V 726		

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V 726	Continued From page 16 manager (CM1) was informed of the missing training records, she stated, "We've called [ACH1] and asked for the information several times, but they haven't responded." Upon being asked for a list of all the patients who were trained at the [ACH1] facility, CM1 immediately provided the current patient status/census which indicated a total of four patients. A review of all four records indicated Patient 6's record also did not contain any training records. 3. While reviewing Patient 2's treatment/ training records from 9/9/10 to 11/1/10, it was noted that the column for the chlorine/chloramine testing were not consistently marked or filled out. Chlorine/ chloramine testing is an integral safety check for the quality of the water used to prepare the dialysate. The treatment records were shown to the RN who said, " It was another nurse who trained the patient, but those should have been marked. Although if they used a bag, the chloramine test does not need to be done." The form was reviewed and there was a spot where it indicated "NA (using bags)". The nurse who trained the patient was a travelling nurse and was no longer working at the facility.	V 726		