

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152597	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 06/15/2012
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NAME OF PROVIDER OR SUPPLIER WELLBOUND OF LAFAYETTE	STREET ADDRESS, CITY, STATE, ZIP CODE 2 EXECUTIVE DR STE B LAFAYETTE, IN 47905
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V0000	<p>This was an ESRD federal recertification survey.</p> <p>Survey Dates: 6/12/12 through 6/15/12</p> <p>Facility #: 011238</p> <p>Medicaid Vendor #: 200843920</p> <p>Surveyor: Bridget Boston, RN, PHNS</p> <p>Census: 48 Total, 11 peritoneal dialysis and 37 home hemodialysis</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN</p> <p>June 21, 2012</p>	V0000	<p>Census: 48 total, 37 peritoneal dialysis and 11 home hemodialysis</p> <p>Correction to distribution of patients on home modalities.</p>	

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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V0111	<p>494.30 IC-SANITARY ENVIRONMENT The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.</p> <p>Based on observation, interview, and review of facility policy, the facility failed to ensure staff followed infection control policies during the provision of care in 5 (observation 3, 4, 5, 6, and 7) of 7 observations and appropriate cleansing solutions were readily available creating the potential to affect all of the facility's 48 current patients.</p> <p>The findings include:</p> <p>1. The facility policy titled "Exposure Control Plan" revision date 6/26/08 stated, "Purpose: To explain the Exposure Control Plan to Employees. Responsibility: All Satellite Healthcare Personnel. Required by: Standards of Practice, OSHA. ... Expose Control puts emphasis on an employer's responsibility for protection healthcare workers and employees from dangerous blood borne infection. Infection Control directives are aimed at the prevention and management of general infection in and among patients. The new Exposure Control Rule focuses on identifying healthcare workers at various degrees of risk to ensure that:</p>	V0111	<p>494.30 IC-Sanitary Environment1-14. Retraining of all center staff will be provided by the Safety Officer and/or Clinical Nurse Manager on the Exposure Control Plan by 7/3/12. Monitoring to prevent recurrence of the deficiency will be done through direct observation of center staff practices during patient care. Audit form to track monitoring is developed and will completed by Safety Officer and/or Clinical Nurse Manager daily for 1 month then weekly starting 7/3/12 (see Exhibit A). Audit results will be reviewed at QAPI scheduled meetings.2, 6, 7. Retraining of all center staff will be provided by the Safety Officer and/or Clinical Nurse Manager on the center policy for Hand Washing by 7/3/12. Monitoring to prevent recurrence of the deficiency will be done through direct observation of center staff practices during patient care. Audit form to track monitoring is developed and will be completed by Safety Officer and/or Clinical Nurse Manager daily for 1 month then weekly starting 7/3/12(see Exhibit A). Audit results will be reviewed at QAPI scheduled meetings.3, 12. An appropriate</p>	07/16/2012

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	<p>... Existing Universal Precautions are employed to reduce the risk of infection by blood borne pathogens. ... Determining the risk classification into each job in the facility best fits and the identification of which specific tasks associated with a job create the risk of exposure to blood borne pathogens: Scheduling the implementation of: Methods of compliance with the Rule covering: ... Housekeeping related equipment, work areas and surfaces, protective covering, waste and waste disposal containers. ... Covered diseases - ... The three most significant are hepatitis B (HBV), Hepatitis C (HBC), and human immunodeficiency virus (HIV). ... Modes of transmission. The pathogens that can transmit these diseases may be present in the blood and other body fluids ... may be present in the peritoneal ... and any other fluids contaminated with blood. ... These pathogens can enter and infect the human body through openings in the skin including cuts, nicks, abrasions, dermatitis, or acne. ... Infection can also gain access to the body through mucous membranes of the eyes, nose, and mouth when these areas are touched with contaminated hands."</p> <p>2. The facility policy titled "Hand Washing" revision date 8/15/10 stated,</p>		<p>surface disinfectant effective against Hepatitis B and TB as directed by the CDC will be used and was implemented on 6/28/12 to disinfect all contact surface areas in the patient treatment rooms by all or any persons who are assigned to terminally disinfect treatment rooms between patients. 4, 5. Retraining of all center staff will be provided by the Safety Officer and/or Clinical Nurse Manager on the center policy for Cleaning and Disinfection of Work Area and Equipment by 7/2/12. Monitoring to prevent recurrence of the deficiency will be done through direct observation of center staff practices during patient care. Audit form to track monitoring is developed and will be completed by Safety Officer and/or Clinical Nurse Manager daily for 1 month then weekly starting 7/3/12 (see Exhibit A). Audit results will be reviewed at QAPI scheduled meetings.8. Trash receptacles in all patient training rooms will be modified to be hands free access by the Satellite Facilities Manager on or by 7/15/12. There will be a 9 inch opening placed in the counter top to drop the trash/refuse into to prevent staff or patients from contamination to or from the pull handle.10, 13. All computer keyboards will have keyboard covers that can be disinfected topically between each patient visit by 7/16/12. All keyboards will be disinfected after</p>				

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	<p>"After contact with a patient or patient's medical equipment; after removal of gloves; or after patient care procedures hands must be disinfected using soap and water or an alcohol based hand rub."</p> <p>3. The facility policy titled "Dialysis Facility Cleaning" revision date 9/9/09 stated, "All germicidal solutions utilized for sanitizing patient care areas will follow Centers for Disease Control (CDC) recommendations for Hepatitis B and TB (tuberculosis)."</p> <p>4. The facility policy, revision date 06/06/11, titled "Cleaning and Disinfection of Work Area and Equipment" stated, "Equipment that is designated as reusable may be a source of environmental contamination unless properly cleaned, disinfected, or sterilized. All equipment with any possibility of being contaminated by blood or other infectious materials shall be thoroughly cleaned and decontaminated following manufactures instructions, between patients. ... All employees shall adhere to Universal Precautions to guard against infection of blood borne pathogens when working around work areas and surfaces that may have been contaminated. All work surfaces shall be thoroughly cleaned and decontaminated immediately or as soon as</p>		<p>each patient visit by the staff member assigned to care for the patient or the center MA. Until keyboard covers are installed, disposable protective covering will be placed over keyboards and replaced between each patient visit. Monitoring to prevent recurrence of the deficiency will be done through direct observation of center staff practices during patient care. Audit form to track monitoring is developed and will be completed by Safety Officer and/or Clinical Nurse Manager daily for 1 month then weekly starting 7/3/12 (see Exhibit A). Audit results will be reviewed at QAPI scheduled meetings.8, 11. All patient personal items were returned to patients as of 6/13/12, patient and caregiver were instructed to bring personal items desired each day and take with them as they leave. To prevent recurrence of the deficiency, all patients will be directed not to leave any personal comfort items in the center when treatment is complete on the first day of admission by the admitting staff. Existing patients will be re-educated at their regular scheduled monthly visit of this policy through written directive and verbal instruction by 7/27/12. This will be audited by the Clinical Nurse Manager through direct observation of admission practices and review of the patient acknowledgement form signed by the new patient on first</p>		

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	<p>feasible after contact with blood or other potentially infectious materials."</p> <p>5. The facility's policy titled "Cleaning and Disinfection of Work Area and Equipment" revision date 8/15/10, stated, "Cleaning of Treatment Related Equipment 1. Machine, chair, blood pressure cuffs, chair side tables, ... are to be wiped down with soap, a detergent, or a detergent germicide between patient treatments. ... In home training venues, most patient encounters are office visits as opposed to dialysis treatments. Also, in home training venues much of the equipment is not shared between patients (e.g. blood pressure cuffs are assigned to a specific patient)."</p> <p>6. . The CDC Morbidity and Mortality Weekly Report (MMWR) October 25, 2002, Volume 51 No. RR-16 "Guideline for Hand Hygiene in Health-Care Settings" states, "Recommendations: Indications for hand washing and hand antisepsis . . . Decontaminate hands before having direct contact with patients . . . Decontaminate hands after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient. Decontaminate hands after removing gloves."</p> <p>7. Observation # 3 was completed on</p>		<p>admit day and review of the existing patients' monthly clinic visit from the month 7/12 (see Exhibit B).12, 13. The painted wooden armoire knobs will be replaced with non-porous knobs which can be disinfected with the surface disinfectant by 7/5/12. Monitoring of disinfecting painted armoire and armoire handles between patients will be done daily for 1 month then weekly using the developed audit tool (see Exhibit A) by 7/5/12 by the safety Officer and/or Clinical Nurse Manager to prevent recurrence of potential cross contamination of surfaces in the patient treatment rooms.14. An appropriate surface disinfectant effective against Hepatitis B and TB as directed by the CDC will be used and was implemented to disinfect all contact surface areas in the patient treatment rooms on 6/28/12 by all or any persons who are assigned to terminally disinfect treatment rooms between patients.</p>				

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	6-13-12 at 9:10 AM. Employee D, a medical assistant, was observed in the hallway outside training rooms 1 through 4 wearing a white disposable gown, face shield, and gloves. She was observed to enter training room 4 and verbally indicated a peritoneal dialysis patient had used the room. She picked up a translucent bag containing a semi - clear liquid and carried it outside of the room to a soiled utility area and, with her gloved hand, opened a door which separated the soiled area from the area identified as "Biohazard" where she then disposed of the solution in a sink. She returned to training room 4 wearing the same gloves as worn to open the door and dispose of the liquid and with the left gloved hand she picked up a bottle of Alcavis 50 from the counter top. With her right gloved hand she opened a door in the above the counter cabinet and placed the bottle inside the cabinet along side other bottles of same product. Then, with same gloved right hand, she pulled on a handle on a lower cabinet door to gain access to a trash receptacle that was housed in this drawer. She removed her gloves and placed them in the trash, then closed the drawer by pushing on the handle with her bare hands. Without any hand hygiene, she donned a new pair of gloves, opened a cabinet door under the sink, and retrieved a bottle labeled "Clorox Disinfecting			

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	<p>Wipes." She was then observed to briefly wipe the reusable sphygmomanometer. She then opened a door on a wooden armoire in the training room by it's wooden pull knob, and placed the item inside the armoire with other packaged items used for dialysis patients. She then quickly wiped, with the same cloth, the top only of a bedside table, the top only of the counter in the training room, the patient treatment chair, and an intravenous (IV) pole. Employee D did not clean the front of the cabinet and the handle used to access the trash and did not clean any part of the armoire door or knob.</p> <p>A. Employee D was interviewed after she had cleaned the room and she indicated she did not wipe off the outside of the Alcavis bottle before she returned to the cabinet and indicated it was not part of her normal cleaning routine. She further indicated all the rooms were set up the same, none of the waste receptacles had a hands free access, all rooms had wooden armoires with wooden handles that housed the hemo and peritoneal dialysis supplies for the training rooms. None of the computer keyboards were covered with a surface which permitted cleaning, and she was not aware of the directions on the Clorox Disinfecting Wipes that stated, "Bleach Free ... active</p>						

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	<p>ingredient dimethyl benzyl ammonium chloride .. use enough wipes for treatment area to remain visibly wet for 4 minutes to disinfect ... let surface dry ... use on hard non porous surfaces."</p> <p>B. On 6/13/12 at 9:15 AM in home training room 2, employee B, a registered nurse, indicated she had cleaned the training room after the last dialysis patient training and had used Clorox Disinfecting Wipes. She indicated that frequently the top wipe is not sufficiently wet by the solution and she needed to pull a wipe from the bottom of the container to be sufficiently wet. She indicated she was not aware of the directions on the Clorox Disinfecting Wipes that state, "Use enough wipes for treatment area to remain visibly wet for 4 minutes to disinfect ... let surface dry ... use on hard non porous surfaces."</p> <p>8. Observation # 4 was completed on 6-13-12 at 9:30 AM in home training room 2, while employee B was observed to provide care, education, and training to patient number 1, a new home hemodialysis patient, and a family member in training with the Nxstage dialysis equipment. Employee B was observed multiple times throughout the training, to open the drawer that housed the trash receptacle with her soiled gloved</p>						

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	<p>hands by the only means available, by pulling on the attached handle, and then closed by pushing on the handle with her bare hands. The patient's family member in training was observed to open and close the trash receptacle multiple times in the same manner as employee B, opened with soiled gloved hands and closed with bare hands. Employee B, the home training nurse, failed to instruct the family member to follow standard hand hygiene protocols and to not touch the contaminated surfaces without decontaminating hands and before proceeding to another task in setting up the NxStage hemodialysis equipment. During the observation, patient # 1 requested employee B to retrieve a stuffed animal from the armoire. Employee B opened the top drawer (one of two drawers) of the armoire and retrieved a stuffed animal and handed to the patient. Also in the drawer were blankets and various wrapped dialysis supplies. Patient number 1 indicated the personal items in the drawer belonged to the patient and were placed there by the patient after he / she arrived for training. During the observation, employee B retrieved, with un-gloved hands, additional items from the upper cabinet area of the wooden armoire cabinet in the training room which housed additional supplies for the dialysis patients. The</p>						

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	<p>armoire and the pull knobs were painted wood.</p> <p>9. On 6/13/12 at 10 AM, patient # 2 was interviewed in training room 4. Patient 2 indicated treatment option was home peritoneal dialysis and that he / she had an diagnoses of peritonitis last August and this clinic visit was for an injection of Epogen, intravenous iron, and to review lab results.</p> <p>10. Observation # 5 was completed on 6-13-12 at 10:30 AM, employee D was observed to enter training room 4. Patient 2 exited training room 4 at 10:15 AM. Employee D closed the computer keyboard without cleansing, picked up paperwork from patient # 2's clinic visit and carried it out of the training room to the nurse's office and then returned to the training room. With gloved hands she opened the bottom cabinet, retrieved a container of Clorox Disinfecting Wipes. She obtained a disposable wipe from the container and briefly wiped the BP cuff and then placed it back on the counter. After cleansing the patient treatment chair, top of counter, and IV pole, she discarded the wipes as she used them. Each time she opened the trash receptacle, she placed her soiled gloved hand on the handle of the cabinet to open the cabinet door to gain access to the housed trash</p>				

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	<p>receptacle, then disposed of the wipe, and pushed the door closed with her bare hands. She then retrieved another wipe from the Clorox wipe container, then continued to wipe off items. She opened the trash receptacle 3 times to throw away the disposable cleaning wipes. After the third time, she removed her gloves and disposed of them in the receptacle and then, with her bare hands, closed the cabinet door. Then, without decontaminating her hands, she picked up the blood pressure cuff and then opened the wooden armoire by the wooden knob and placed the BP cuff inside the cabinet along side the other dialysis supplies that included a tympanic thermometer, wrapped gauze, adhesive tape used for dressings, and other individually wrapped dialysis supplies used for peritoneal and hemodialysis patients.</p> <p>11. Observation # 6 was completed on 6-13-12 at 10:40 AM in home training room 4. Employee D opened the top drawer in the wood armoire and revealed a blanket in the drawer with the wrapped peritoneal dialysis supplies, individually wrapped saline bags and tubing. Employee D indicated the blanket belonged to the facility, and she did not know who cleaned these blankets and when.</p>						

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	<p>12. On 6/13/12 at 1:30 PM, employee A indicated the training rooms were set up to resemble a home like atmosphere and that is why the trash was behind a door and the armoire was wooden. She said the staff were to use paper towels to open the door to expose the trash can and then leave it open until no longer needed. She indicated the facility did not have any other cleansing solution and Wellbound corporation had instructed the facility to use Clorox Disinfecting Wipes for all patient care areas. She was unable to find a policy and procedure that instructed the staff to use a particular product or concentration of bleach solution and that addressed how the staff were to clean the porous wood storage units and knobs in the training rooms.</p> <p>13. Observation # 7 was completed on 6-15-12 at 11:50 AM in home training room 1 with employee C, a registered nurse, who indicated she had completed training with patient number 7, a new patient that had completed a second day of peritoneal dialysis training. She indicated she was cleaning training room 1 and preparing for the next patient. She was observed to open the trash receptacle by pulling on the handle multiple times and did so with soiled gloved hands, then pushed to close with her bare hands. Then, without decontaminating her hands,</p>						

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	<p>she opened the wooden armoire by pulling on the wooden handles to place items inside. There was no attempt to decontaminate the armoire, the wooden knobs on the armoire, and the computer keyboard. She indicated the computer keyboard was used by her to document during the previous patient visit and she used the keyboard routinely in every training room to document during the clinic visits. She indicated the keyboards do not have and have never had any covers.</p> <p>14. The facility failed to evidence an effective cleanser was available for the cleansing and disinfecting all surfaces that are potentially and actually contaminated by patients and staff during clinic visits and patient training sessions and was effective on the pathogens that may be present in the blood and other body fluids. The product used in the facility was labeled "Clorox Disinfecting Wipes" failed to clearly state the product was appropriate and effective for use by the dialysis unit. The label stated, "Bleach free ... kills 99.9 % of germs including viruses that cause colds and flu influenza A2 and rhinovirus ... also effective against common bacteria such as staphylococcus aureus, salmonella, and E. coli ... Use enough wipes for treatment area to remain visibly wet for 4 minutes</p>			

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	to disinfect ... let surface dry ... use on hard non porous surfaces."			

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V0112	<p>494.30(a) IC-CDC MMWR 2001</p> <p>The facility must demonstrate that it follows standard infection control precautions by implementing-</p> <p>(1)(i) The recommendations (with the exception of screening for hepatitis C), found in "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html.</p> <p>The recommendation found under section header "HBV-Infected Patients", found on pages 27 and 28 of RR05 ("Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients"), concerning isolation rooms, must be complied with by February 9, 2009.</p> <p>Based on observation, interview, and review of facility policy, the facility failed to implement and ensure staff provided care and completed tasks following</p>	V0112	494.30(a) IC-CDC MMWR 20012, 6, 7. Retraining of all center staff will be provided by the Safety Officer and/or Clinical Nurse Manager on the center policy for	07/16/2012			

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	<p>standard infection control precautions during the provision of care in 5 (#s 2, 4, 5, 6, 7, 8, and 9) of 7 observations and failed to ensure appropriate disinfecting and sanitizing solutions were readily available creating the potential to affect all of the facility's 48 current patients.</p> <p>The findings include:</p> <p>1. The facility policy titled "Exposure Control Plan" revision date 6/26/08 stated, "Purpose: To explain the Exposure Control Plan to Employees. Responsibility: All Satellite Healthcare Personnel. Required by: Standards of Practice, OSHA. ... Expose Control puts emphasis on an employer's responsibility for protection healthcare workers and employees from dangerous blood borne infection. Infection Control directives are aimed at the prevention and management of general infection in and among patients. The new Exposure Control Rule focuses on identifying healthcare workers at various degrees of risk to ensure that: ... Existing Universal Precautions are employed to reduce the risk of infection by blood borne pathogens. ... Determining the risk classification into each job in the facility best fits and the identification of which specific tasks associated with a job create the risk of exposure to blood borne pathogens:</p>		<p>Hand Washing by 7/3/12. Monitoring to prevent recurrence of the deficiency will be done through direct observation of center staff practices during patient care. Audit form to track monitoring is developed and will be completed by Safety Officer and/or Clinical Nurse Manager daily for 1 month then weekly starting 7/3/12(see Exhibit A). Audit results will be reviewed at QAPI scheduled meetings.3, 12. An appropriate surface disinfectant effective against Hepatitis B and TB as directed by the CDC will be used and was implemented on 6/28/12 to disinfect all contact surface areas in the patient treatment rooms by all or any persons who are assigned to terminally disinfect treatment rooms between patients. 4, 5. Retraining of all center staff will be provided by the Safety Officer and/or Clinical Nurse Manager on the center policy for Cleaning and Disinfection of Work Area and Equipment by 7/2/12. Monitoring to prevent recurrence of the deficiency will be done through direct observation of center staff practices during patient care. Audit form to track monitoring is developed and will be completed by Safety Officer and/or Clinical Nurse Manager daily for 1 month then weekly starting 7/3/12 (see Exhibit A). Audit results will be reviewed at QAPI scheduled meetings.8. Trash receptacles in</p>				

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	<p>Scheduling the implementation of: Methods of compliance with the Rule covering: ... Housekeeping related equipment, work areas and surfaces, protective covering, waste and waste disposal containers. ... Covered diseases - ... The three most significant are hepatitis B (HBV), Hepatitis C (HBC), and human immunodeficiency virus (HIV). ... Modes of transmission. The pathogens that can transmit these diseases may be present in the blood and other body fluids ... may be present in the peritoneal ... and any other fluids contaminated with blood. ... These pathogens can enter and infect the human body through openings in the skin including cuts, nicks, abrasions, dermatitis, or acne. ... Infection can also gain access to the body through mucous membranes of the eyes, nose, and mouth when these areas are touched with contaminated hands."</p> <p>2. The facility policy titled "Hand Washing" revision date 8/15/10 stated, "After contact with a patient or patient's medical equipment; after removal of gloves; or after patient care procedures hands must be disinfected using soap and water or an alcohol based hand rub."</p> <p>3. The facility policy titled "Dialysis Facility Cleaning" revision date 9/9/09</p>		<p>all patient training rooms will be modified to be hands free access by the Satellite Facilities Manager on or by 7/15/12. There will be a 9 inch opening placed in the counter top to drop the trash/refuse into to prevent staff or patients from contamination to or from the pull handle.10, 13. All computer keyboards will have keyboard covers that can be disinfected topically between each patient visit by 7/16/12. All keyboards will be disinfected after each patient visit by the staff member assigned to care for the patient or the center MA. Until keyboard covers are installed, disposable protective covering will be placed over keyboards and replaced between each patient visit. Monitoring to prevent recurrence of the deficiency will be done through direct observation of center staff practices during patient care. Audit form to track monitoring is developed and will be completed by Safety Officer and/or Clinical Nurse Manager daily for 1 month then weekly starting 7/3/12 (see Exhibit A). Audit results will be reviewed at QAPI scheduled meetings.8, 11. All patient personal items were returned to patients as of 6/13/12, patient and caregiver were instructed to bring personal items desired each day and take with them as they leave. To prevent recurrence of the deficiency, all patients will be directed not to leave any personal</p>	

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	<p>stated, "All germicidal solutions utilized for sanitizing patient care areas will follow Centers for Disease Control (CDC) recommendations for Hepatitis B and TB (tuberculosis)."</p> <p>4. The facility policy, revision date 06/06/11, titled "Cleaning and Disinfection of Work Area and Equipment" stated, "Equipment that is designated as reusable may be a source of environmental contamination unless properly cleaned, disinfected, or sterilized. All equipment with any possibility of being contaminated by blood or other infectious materials shall be thoroughly cleaned and decontaminated following manufactures instructions, between patients. ... All employees shall adhere to Universal Precautions to guard against infection of blood borne pathogens when working around work areas and surfaces that may have been contaminated. All work surfaces shall be thoroughly cleaned and decontaminated immediately or as soon as feasible after contact with blood or other potentially infectious materials."</p> <p>5. The facility's policy titled "Cleaning and Disinfection of Work Area and Equipment" revision date 8/15/10, stated, "Cleaning of Treatment Related Equipment 1. Machine, chair, blood</p>		<p>comfort items in the center when treatment is complete on the first day of admission by the admitting staff. Existing patients will be re-educated at their regular scheduled monthly visit of this policy through written directive and verbal instruction by 7/27/12. This will be audited by the Clinical Nurse Manager through direct observation of admission practices and review of the patient acknowledgement form signed by the new patient on first admit day and review of the existing patients' monthly clinic visit from the month 7/12 (see Exhibit B).12, 13. The painted wooden armoire knobs will be replaced with non-porous knobs which can be disinfected with the surface disinfectant by 7/5/12. Monitoring of disinfecting painted armoire and armoire handles between patients will be done daily for 1 month then weekly using the developed audit tool (see Exhibit A) by 7/5/12 by the safety Officer and/or Clinical Nurse Manager to prevent recurrence of potential cross contamination of surfaces in the patient treatment rooms.14. An appropriate surface disinfectant effective against Hepatitis B and TB as directed by the CDC will be used and was implemented to disinfect all contact surface areas in the patient treatment rooms on 6/28/12 by all or any persons who are assigned to terminally disinfect treatment rooms</p>		

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	<p>pressure cuffs, chair side tables, ... are to be wiped down with soap, a detergent, or a detergent germicide between patient treatments. ... In home training venues, most patient encounters are office visits as opposed to dialysis treatments. Also, in home training venues much of the equipment is not shared between patients (e.g. blood pressure cuffs are assigned to a specific patient)."</p> <p>6. . The CDC Morbidity and Mortality Weekly Report (MMWR) October 25, 2002, Volume 51 No. RR-16 "Guideline for Hand Hygiene in Health-Care Settings" states, "Recommendations: Indications for hand washing and hand antisepsis . . . Decontaminate hands before having direct contact with patients . . . Decontaminate hands after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient. Decontaminate hands after removing gloves."</p> <p>7. Observation # 3 was completed on 6-13-12 at 9:10 AM. Employee D, a medical assistant, was observed in the hallway outside training rooms 1 through 4 wearing a white disposable gown, face shield, and gloves. She was observed to enter training room 4 and verbally indicated a peritoneal dialysis patient had used the room. She picked up a</p>		<p>between patients. 1-14. Retraining of all center staff will be provided by the Safety Officer and/or Clinical Nurse Manager on the Exposure Control Plan by 7/3/12. Monitoring to prevent recurrence of the deficiency will be done through direct observation of center staff practices during patient care. Audit form to track monitoring is developed and will completed by Safety Officer and/or Clinical Nurse Manager daily for 1 month then weekly starting 7/3/12 (see Exhibit A). Audit results will be reviewed at QAPI scheduled meetings.</p>		

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	translucent bag containing a semi - clear liquid and carried it outside of the room to a soiled utility area and, with her gloved hand, opened a door which separated the soiled area from the area identified as 'Biohazard" where she then disposed of the solution in a sink. She returned to training room 4 wearing the same gloves as worn to open the door and dispose of the liquid and with the left gloved hand she picked up a bottle of Alcavis 50 from the counter top. With her right gloved hand she opened a door in the above the counter cabinet and placed the bottle inside the cabinet along side other bottles of same product. Then, with same gloved right hand, she pulled on a handle on a lower cabinet door to gain access to a trash receptacle that was housed in this drawer. She removed her gloves and placed them in the trash, then closed the drawer by pushing on the handle with her bare hands. Without any hand hygiene, she donned a new pair of gloves, opened a cabinet door under the sink, and retrieved a bottle labeled "Clorox Disinfecting Wipes." She was then observed to briefly wipe the reusable sphygmomanometer. She then opened a door on a wooden armoire in the training room by it's wooden pull knob, and placed the item inside the armoire with other packaged items used for dialysis patients. She then quickly wiped, with the same cloth, the			

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	<p>top only of a bedside table, the top only of the counter in the training room, the patient treatment chair, and an intravenous (IV) pole. Employee D did not clean the front of the cabinet and the handle used to access the trash and did not clean any part of the armoire door or knob.</p> <p>A. Employee D was interviewed after she had cleaned the room and she indicated she did not wipe off the outside of the Alcavis bottle before she returned to the cabinet and indicated it was not part of her normal cleaning routine. She further indicated all the rooms were set up the same, none of the waste receptacles had a hands free access, all rooms had wooden armoires with wooden handles that housed the hemo and peritoneal dialysis supplies for the training rooms. None of the computer keyboards were covered with a surface which permitted cleaning, and she was not aware of the directions on the Clorox Disinfecting Wipes that stated, "Bleach Free ... active ingredient dimethyl benzyl ammonium chloride .. use enough wipes for treatment area to remain visibly wet for 4 minutes to disinfect ... let surface dry ... use on hard non porous surfaces."</p> <p>B. On 6/13/12 at 9:15 AM in home training room 2, employee B, a registered</p>						

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	<p>nurse, indicated she had cleaned the training room after the last dialysis patient training and had used Clorox Disinfecting Wipes. She indicated that frequently the top wipe is not sufficiently wet by the solution and she needed to pull a wipe from the bottom of the container to be sufficiently wet. She indicated she was not aware of the directions on the Clorox Disinfecting Wipes that state, "Use enough wipes for treatment area to remain visibly wet for 4 minutes to disinfect ... let surface dry ... use on hard non porous surfaces."</p> <p>8. Observation # 4 was completed on 6-13-12 at 9:30 AM in home training room 2, while employee B was observed to provide care, education, and training to patient number 1, a new home hemodialysis patient, and a family member in training with the Nxstage dialysis equipment. Employee B was observed multiple times throughout the training, to open the drawer that housed the trash receptacle with her soiled gloved hands by the only means available, by pulling on the attached handle, and then closed by pushing on the handle with her bare hands. The patient's family member in training was observed to open and close the trash receptacle multiple times in the same manner as employee B, opened with soiled gloved hands and</p>						

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	<p>closed with bare hands. Employee B, the home training nurse, failed to instruct the family member to follow standard hand hygiene protocols and to not touch the contaminated surfaces without decontaminating hands and before proceeding to another task in setting up the NxStage hemodialysis equipment. During the observation, patient # 1 requested employee B to retrieve a stuffed animal from the armoire. Employee B opened the top drawer (one of two drawers) of the armoire and retrieved a stuffed animal and handed to the patient. Also in the drawer were blankets and various wrapped dialysis supplies. Patient number 1 indicated the personal items in the drawer belonged to the patient and were placed there by the patient after he / she arrived for training. During the observation, employee B retrieved, with un-gloved hands, additional items from the upper cabinet area of the wooden armoire cabinet in the training room which housed additional supplies for the dialysis patients. The armoire and the pull knobs were painted wood.</p> <p>9. On 6/13/12 at 10 AM, patient # 2 was interviewed in training room 4. Patient 2 indicated treatment option was home peritoneal dialysis and that he / she had an diagnoses of peritonitis last August and</p>			

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	<p>this clinic visit was for an injection of Epogen, intravenous iron, and to review lab results.</p> <p>10. Observation # 5 was completed on 6-13-12 at 10:30 AM, employee D was observed to enter training room 4. Patient 2 exited training room 4 at 10:15 AM. Employee D closed the computer keyboard without cleansing, picked up paperwork from patient # 2's clinic visit and carried it out of the training room to the nurse's office and then returned to the training room. With gloved hands she opened the bottom cabinet, retrieved a container of Clorox Disinfecting Wipes. She obtained a disposable wipe from the container and briefly wiped the BP cuff and then placed it back on the counter. After cleansing the patient treatment chair, top of counter, and IV pole, she discarded the wipes as she used them. Each time she opened the trash receptacle, she placed her soiled gloved hand on the handle of the cabinet to open the cabinet door to gain access to the housed trash receptacle, then disposed of the wipe, and pushed the door closed with her bare hands. She then retrieved another wipe from the Clorox wipe container, then continued to wipe off items. She opened the trash receptacle 3 times to throw away the disposable cleaning wipes. After the third time, she removed her gloves and</p>						

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	<p>disposed of them in the receptacle and then, with her bare hands, closed the cabinet door. Then, without decontaminating her hands, she picked up the blood pressure cuff and then opened the wooden armoire by the wooden knob and placed the BP cuff inside the cabinet along side the other dialysis supplies that included a tympanic thermometer, wrapped gauze, adhesive tape used for dressings, and other individually wrapped dialysis supplies used for peritoneal and hemodialysis patients.</p> <p>11. Observation # 6 was completed on 6-13-12 at 10:40 AM in home training room 4. Employee D opened the top drawer in the wood armoire and revealed a blanket in the drawer with the wrapped peritoneal dialysis supplies, individually wrapped saline bags and tubing. Employee D indicated the blanket belonged to the facility, and she did not know who cleaned these blankets and when.</p> <p>12. On 6/13/12 at 1:30 PM, employee A indicated the training rooms were set up to resemble a home like atmosphere and that is why the trash was behind a door and the armoire was wooden. She said the staff were to use paper towels to open the door to expose the trash can and then leave it open until no longer needed. She</p>			

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	<p>indicated the facility did not have any other cleansing solution and Wellbound corporation had instructed the facility to use Clorox Disinfecting Wipes for all patient care areas. She was unable to find a policy and procedure that instructed the staff to use a particular product or concentration of bleach solution and that addressed how the staff were to clean the porous wood storage units and knobs in the training rooms.</p> <p>13. Observation # 7 was completed on 6-15-12 at 11:50 AM in home training room 1 with employee C, a registered nurse, who indicated she had completed training with patient number 7, a new patient that had completed a second day of peritoneal dialysis training. She indicated she was cleaning training room 1 and preparing for the next patient. She was observed to open the trash receptacle by pulling on the handle multiple times and did so with soiled gloved hands, then pushed to close with her bare hands. Then, without decontaminating her hands, she opened the wooden armoire by pulling on the wooden handles to place items inside. There was no attempt to decontaminate the armoire, the wooden knobs on the armoire, and the computer keyboard. She indicated the computer keyboard was used by her to document during the previous patient visit and she</p>						

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	<p>used the keyboard routinely in every training room to document during the clinic visits. She indicated the keyboards do not have and have never had any covers.</p> <p>14. The facility failed to evidence an effective cleanser was available for the cleansing and disinfecting all surfaces that are potentially and actually contaminated by patients and staff during clinic visits and patient training sessions and was effective on the pathogens that may be present in the blood and other body fluids. The product used in the facility was labeled "Clorox Disinfecting Wipes" failed to clearly state the product was appropriate and effective for use by the dialysis unit. The label stated, "Bleach free ... kills 99.9 % of germs including viruses that cause colds and flu influenza A2 and rhinovirus ... also effective against common bacteria such as staphylococcus aureus, salmonella, and E. coli ... Use enough wipes for treatment area to remain visibly wet for 4 minutes to disinfect ... let surface dry ... use on hard non porous surfaces."</p>				

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V0122	<p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing-</p> <p>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]</p> <p>(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.</p> <p>Based on observation, policy review, and interview the facility failed to ensure the facility implemented standard infection control precautions and followed maintained procedures in accordance with accepted health procedures in the cleaning and disinfection of contaminated surfaces and equipment in 5 of 7 observations with the potential to effect all 48 dialysis patients. (observation # 3, 4, 5, 6, and 7)</p> <p>The findings include:</p> <p>1. The facility policy titled "Exposure Control Plan" revision date 6/26/08 stated, "Purpose: To explain the Exposure Control Plan to Employees. Responsibility: All Satellite Healthcare Personnel. Required by: Standards of Practice, OSHA. ... Expose Control puts emphasis on an employer's responsibility for protection healthcare workers and employees from dangerous blood borne infection. Infection Control directives are</p>	V0122	<p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL</p> <p>1-14. Retraining of all center staff will be provided by the Safety Officer and/or Clinical Nurse Manager on the Exposure Control Plan by 7/3/12. Monitoring to prevent recurrence of the deficiency will be done through direct observation of center staff practices during patient care. Audit form to track monitoring is developed and will completed by Safety Officer and/or Clinical Nurse Manager daily for 1 month then weekly starting 7/3/12 (see Exhibit A). Audit results will be reviewed at QAPI scheduled meetings.</p> <p>2, 6, 7. Retraining of all center staff will be provided by the Safety Officer and/or Clinical Nurse Manager on the center policy for Hand Washing by 7/3/12. Monitoring to prevent recurrence of the deficiency will be done through direct observation of center staff practices during patient care.</p>	07/16/2012			

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	<p>aimed at the prevention and management of general infection in and among patients. The new Exposure Control Rule focuses on identifying healthcare workers at various degrees of risk to ensure that: ... Existing Universal Precautions are employed to reduce the risk of infection by blood borne pathogens. ... Determining the risk classification into each job in the facility best fits and the identification of which specific tasks associated with a job create the risk of exposure to blood borne pathogens: Scheduling the implementation of: Methods of compliance with the Rule covering: ... Housekeeping related equipment, work areas and surfaces, protective covering, waste and waste disposal containers. ... Covered diseases - ... The three most significant are hepatitis B (HBV), Hepatitis C (HBC), and human immunodeficiency virus (HIV). ... Modes of transmission. The pathogens that can transmit these diseases may be present in the blood and other body fluids ... may be present in the peritoneal ... and any other fluids contaminated with blood. ... These pathogens can enter and infect the human body through openings in the skin including cuts, nicks, abrasions, dermatitis, or acne. ... Infection can also gain access to the body through mucous membranes of the eyes, nose, and mouth</p>		<p>Audit form to track monitoring is developed and will be completed by Safety Officer and/or Clinical Nurse Manager daily for 1 month then weekly starting 7/3/12(see Exhibit A). Audit results will be reviewed at QAPI scheduled meetings. 3, 12. An appropriate surface disinfectant effective against Hepatitis B and TB as directed by the CDC will be used and was implemented on 6/28/12 to disinfect all contact surface areas in the patient treatment rooms by all or any persons who are assigned to terminally disinfect treatment rooms between patients. 4, 5. Retraining of all center staff will be provided by the Safety Officer and/or Clinical Nurse Manager on the center policy for Cleaning and Disinfection of Work Area and Equipment by 7/2/12. Monitoring to prevent recurrence of the deficiency will be done through direct observation of center staff practices during patient care. Audit form to track monitoring is developed and will be completed by Safety Officer and/or Clinical Nurse Manager daily for 1 month then weekly starting 7/3/12 (see Exhibit A). Audit results will be reviewed at QAPI scheduled meetings. 8. Trash receptacles in all patient training rooms will be modified to be hands free access by the Satellite Facilities Manager on or</p>				

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	<p>when these areas are touched with contaminated hands."</p> <p>2. The facility policy titled "Hand Washing" revision date 8/15/10 stated, "After contact with a patient or patient's medical equipment; after removal of gloves; or after patient care procedures hands must be disinfected using soap and water or an alcohol based hand rub."</p> <p>3. The facility policy titled "Dialysis Facility Cleaning" revision date 9/9/09 stated, "All germicidal solutions utilized for sanitizing patient care areas will follow Centers for Disease Control (CDC) recommendations for Hepatitis B and TB (tuberculosis)."</p> <p>4. The facility policy, revision date 06/06/11, titled "Cleaning and Disinfection of Work Area and Equipment" stated, "Equipment that is designated as reusable may be a source of environmental contamination unless properly cleaned, disinfected, or sterilized. All equipment with any possibility of being contaminated by blood or other infectious materials shall be thoroughly cleaned and decontaminated following manufactures instructions, between patients. ... All employees shall adhere to Universal Precautions to guard against infection of</p>		<p>by 7/15/12. There will be a 9 inch opening placed in the counter top to drop the trash/refuse into to prevent staff or patients from contamination to or from the pull handle.</p> <p>10, 13. All computer keyboards will have keyboard covers that can be disinfected topically between each patient visit by 7/16/12. All keyboards will be disinfected after each patient visit by the staff member assigned to care for the patient or the center MA. Until keyboard covers are installed, disposable protective covering will be placed over keyboards and replaced between each patient visit. Monitoring to prevent recurrence of the deficiency will be done through direct observation of center staff practices during patient care. Audit form to track monitoring is developed and will be completed by Safety Officer and/or Clinical Nurse Manager daily for 1 month then weekly starting 7/3/12 (see Exhibit A). Audit results will be reviewed at QAPI scheduled meetings.</p> <p>8, 11. All patient personal items were returned to patients as of 6/13/12, patient and caregiver were instructed to bring personal items desired each day and take with them as they leave. To prevent recurrence of the deficiency, all patients will be directed not to leave any personal comfort items in the center when treatment is complete on the first</p>		

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	<p>blood borne pathogens when working around work areas and surfaces that may have been contaminated. All work surfaces shall be thoroughly cleaned and decontaminated immediately or as soon as feasible after contact with blood or other potentially infectious materials."</p> <p>5. The facility's policy titled "Cleaning and Disinfection of Work Area and Equipment" revision date 8/15/10, stated, "Cleaning of Treatment Related Equipment 1. Machine, chair, blood pressure cuffs, chair side tables, ... are to be wiped down with soap, a detergent, or a detergent germicide between patient treatments. ... In home training venues, most patient encounters are office visits as opposed to dialysis treatments. Also, in home training venues much of the equipment is not shared between patients (e.g. blood pressure cuffs are assigned to a specific patient)."</p> <p>6. . The CDC Morbidity and Mortality Weekly Report (MMWR) October 25, 2002, Volume 51 No. RR-16 "Guideline for Hand Hygiene in Health-Care Settings" states, "Recommendations: Indications for hand washing and hand antisepsis . . . Decontaminate hands before having direct contact with patients . . . Decontaminate hands after contact with inanimate objects (including medical</p>		<p>day of admission by the admitting staff. Existing patients will be re-educated at their regular scheduled monthly visit of this policy through written directive and verbal instruction by 7/27/12. This will be audited by the Clinical Nurse Manager through direct observation of admission practices and review of the patient acknowledgement form signed by the new patient on first admit day and review of the existing patients' monthly clinic visit from the month 7/12 (see Exhibit B).</p> <p>12, 13. The painted wooden armoire knobs will be replaced with non-porous knobs which can be disinfected with the surface disinfectant by 7/5/12. Monitoring of disinfecting painted armoire and armoire handles between patients will be done daily for 1 month then weekly using the developed audit tool by 7/5/12 (see Exhibit A) by the safety Officer and/or Clinical Nurse Manager to prevent recurrence of potential cross contamination of surfaces in the patient treatment rooms.</p> <p>14. An appropriate surface disinfectant effective against Hepatitis B and TB as directed by the CDC will be used and was implemented to disinfect all contact surface areas in the patient treatment rooms on 6/28/12 by all or any persons who are assigned to terminally disinfect treatment rooms</p>				

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	<p>equipment) in the immediate vicinity of the patient. Decontaminate hands after removing gloves."</p> <p>7. Observation # 3 was completed on 6-13-12 at 9:10 AM. Employee D, a medical assistant, was observed in the hallway outside training rooms 1 through 4 wearing a white disposable gown, face shield, and gloves. She was observed to enter training room 4 and verbally indicated a peritoneal dialysis patient had used the room. She picked up a translucent bag containing a semi - clear liquid and carried it outside of the room to a soiled utility area and, with her gloved hand, opened a door which separated the soiled area from the area identified as "Biohazard" where she then disposed of the solution in a sink. She returned to training room 4 wearing the same gloves as worn to open the door and dispose of the liquid and with the left gloved hand she picked up a bottle of Alcavis 50 from the counter top. With her right gloved hand she opened a door in the above the counter cabinet and placed the bottle inside the cabinet along side other bottles of same product. Then, with same gloved right hand, she pulled on a handle on a lower cabinet door to gain access to a trash receptacle that was housed in this drawer. She removed her gloves and placed them in the trash, then closed the</p>		between patients.		

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	<p>drawer by pushing on the handle with her bare hands. Without any hand hygiene, she donned a new pair of gloves, opened a cabinet door under the sink, and retrieved a bottle labeled "Clorox Disinfecting Wipes." She was then observed to briefly wipe the reusable sphygmomanometer. She then opened a door on a wooden armoire in the training room by it's wooden pull knob, and placed the item inside the armoire with other packaged items used for dialysis patients. She then quickly wiped, with the same cloth, the top only of a bedside table, the top only of the counter in the training room, the patient treatment chair, and an intravenous (IV) pole. Employee D did not clean the front of the cabinet and the handle used to access the trash and did not clean any part of the armoire door or knob.</p> <p>A. Employee D was interviewed after she had cleaned the room and she indicated she did not wipe off the outside of the Alcavis bottle before she returned to the cabinet and indicated it was not part of her normal cleaning routine. She further indicated all the rooms were set up the same, none of the waste receptacles had a hands free access, all rooms had wooden armoires with wooden handles that housed the hemo and peritoneal dialysis supplies for the training rooms.</p>			

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	<p>None of the computer keyboards were covered with a surface which permitted cleaning, and she was not aware of the directions on the Clorox Disinfecting Wipes that stated, "Bleach Free ... active ingredient dimethyl benzyl ammonium chloride .. use enough wipes for treatment area to remain visibly wet for 4 minutes to disinfect ... let surface dry ... use on hard non porous surfaces."</p> <p>B. On 6/13/12 at 9:15 AM in home training room 2, employee B, a registered nurse, indicated she had cleaned the training room after the last dialysis patient training and had used Clorox Disinfecting Wipes. She indicated that frequently the top wipe is not sufficiently wet by the solution and she needed to pull a wipe from the bottom of the container to be sufficiently wet. She indicated she was not aware of the directions on the Clorox Disinfecting Wipes that state, "Use enough wipes for treatment area to remain visibly wet for 4 minutes to disinfect ... let surface dry ... use on hard non porous surfaces."</p> <p>8. Observation # 4 was completed on 6-13-12 at 9:30 AM in home training room 2, while employee B was observed to provide care, education, and training to patient number 1, a new home hemodialysis patient, and a family</p>						

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	<p>member in training with the Nxstage dialysis equipment. Employee B was observed multiple times throughout the training, to open the drawer that housed the trash receptacle with her soiled gloved hands by the only means available, by pulling on the attached handle, and then closed by pushing on the handle with her bare hands. The patient's family member in training was observed to open and close the trash receptacle multiple times in the same manner as employee B, opened with soiled gloved hands and closed with bare hands. Employee B, the home training nurse, failed to instruct the family member to follow standard hand hygiene protocols and to not touch the contaminated surfaces without decontaminating hands and before proceeding to another task in setting up the NxStage hemodialysis equipment. During the observation, patient # 1 requested employee B to retrieve a stuffed animal from the armoire. Employee B opened the top drawer (one of two drawers) of the armoire and retrieved a stuffed animal and handed to the patient. Also in the drawer were blankets and various wrapped dialysis supplies. Patient number 1 indicated the personal items in the drawer belonged to the patient and were placed there by the patient after he / she arrived for training. During the observation, employee B</p>			

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	<p>retrieved, with un-gloved hands, additional items from the upper cabinet area of the wooden armoire cabinet in the training room which housed additional supplies for the dialysis patients. The armoire and the pull knobs were painted wood.</p> <p>9. On 6/13/12 at 10 AM, patient # 2 was interviewed in training room 4. Patient 2 indicated treatment option was home peritoneal dialysis and that he / she had an diagnoses of peritonitis last August and this clinic visit was for an injection of Epogen, intravenous iron, and to review lab results.</p> <p>10. Observation # 5 was completed on 6-13-12 at 10:30 AM, employee D was observed to enter training room 4. Patient 2 exited training room 4 at 10:15 AM. Employee D closed the computer keyboard without cleansing, picked up paperwork from patient # 2's clinic visit and carried it out of the training room to the nurse's office and then returned to the training room. With gloved hands she opened the bottom cabinet, retrieved a container of Clorox Disinfecting Wipes. She obtained a disposable wipe from the container and briefly wiped the BP cuff and then placed it back on the counter. After cleansing the patient treatment chair, top of counter, and IV pole, she</p>				

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	<p>discarded the wipes as she used them. Each time she opened the trash receptacle, she placed her soiled gloved hand on the handle of the cabinet to open the cabinet door to gain access to the housed trash receptacle, then disposed of the wipe, and pushed the door closed with her bare hands. She then retrieved another wipe from the Clorox wipe container, then continued to wipe off items. She opened the trash receptacle 3 times to throw away the disposable cleaning wipes. After the third time, she removed her gloves and disposed of them in the receptacle and then, with her bare hands, closed the cabinet door. Then, without decontaminating her hands, she picked up the blood pressure cuff and then opened the wooden armoire by the wooden knob and placed the BP cuff inside the cabinet along side the other dialysis supplies that included a tympanic thermometer, wrapped gauze, adhesive tape used for dressings, and other individually wrapped dialysis supplies used for peritoneal and hemodialysis patients.</p> <p>11. Observation # 6 was completed on 6-13-12 at 10:40 AM in home training room 4. Employee D opened the top drawer in the wood armoire and revealed a blanket in the drawer with the wrapped peritoneal dialysis supplies, individually wrapped saline bags and tubing.</p>						

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	<p>Employee D indicated the blanket belonged to the facility, and she did not know who cleaned these blankets and when.</p> <p>12. On 6/13/12 at 1:30 PM, employee A indicated the training rooms were set up to resemble a home like atmosphere and that is why the trash was behind a door and the armoire was wooden. She said the staff were to use paper towels to open the door to expose the trash can and then leave it open until no longer needed. She indicated the facility did not have any other cleansing solution and Wellbound corporation had instructed the facility to use Clorox Disinfecting Wipes for all patient care areas. She was unable to find a policy and procedure that instructed the staff to use a particular product or concentration of bleach solution and that addressed how the staff were to clean the porous wood storage units and knobs in the training rooms.</p> <p>13. Observation # 7 was completed on 6-15-12 at 11:50 AM in home training room 1 with employee C, a registered nurse, who indicated she had completed training with patient number 7, a new patient that had completed a second day of peritoneal dialysis training. She indicated she was cleaning training room 1 and preparing for the next patient. She</p>						

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	<p>was observed to open the trash receptacle by pulling on the handle multiple times and did so with soiled gloved hands, then pushed to close with her bare hands. Then, without decontaminating her hands, she opened the wooden armoire by pulling on the wooden handles to place items inside. There was no attempt to decontaminate the armoire, the wooden knobs on the armoire, and the computer keyboard. She indicated the computer keyboard was used by her to document during the previous patient visit and she used the keyboard routinely in every training room to document during the clinic visits. She indicated the keyboards do not have and have never had any covers.</p> <p>14. The facility failed to evidence an effective cleanser was available for the cleansing and disinfecting all surfaces that are potentially and actually contaminated by patients and staff during clinic visits and patient training sessions and was effective on the pathogens that may be present in the blood and other body fluids. The product used in the facility was labeled "Clorox Disinfecting Wipes" failed to clearly state the product was appropriate and effective for use by the dialysis unit. The label stated, "Bleach free ... kills 99.9 % of germs including viruses that cause colds and flu influenza</p>						

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	A2 and rhinovirus ... also effective against common bacteria such as staphylococcus aureus, salmonella, and E. coli ... Use enough wipes for treatment area to remain visibly wet for 4 minutes to disinfect ... let surface dry ... use on hard non porous surfaces."			

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V0585	<p>494.100(a)(3) H-TRAIN CONTENT INCLUDES ER PREP HOME PTS The training must-</p> <p>(3) Be conducted for each home dialysis patient and address the specific needs of the patient, in the following areas:</p> <p>(i) The nature and management of ESRD. (ii) The full range of techniques associated with the treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care. (iii) How to detect, report, and manage potential dialysis complications, including water treatment problems. (iv) Availability of support resources and how to access and use resources. (v) How to self-monitor health status and record and report health status information. (vi) How to handle medical and non-medical emergencies. (vii) Infection control precautions. (viii) Proper waste storage and disposal procedures.</p> <p>Based on clinical record review and interview, the facility failed to ensure training was conducted and documented to the specific needs of the patient for 1 of 2 clinical records reviewed of patients who reside in an extended care facility (ECF) and who received their peritoneal dialysis treatments from the extended care staff with the potential to effect all 4 dialysis patients that reside in an extended</p>	V0585	<p>494.100(a)(3) H-TRAIN CONTENT INCLUDES ER PREP HOME PTS 1-4. Retraining for the ECF will be conducted to include all specific needs for the home dialysis patient residing in said ECF to include the following areas: nature and management of ESRD, full range of techniques associated with the modality selected including effective use of</p>	07/24/2012			

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	<p>care facility. (Patient 6)</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Clinical record # 6, start of care 6/11/08, evidenced the patient resided in an ECF and the facility staff were completing the patient's peritoneal dialysis daily beginning May 16 through June 15, 2012, date of survey exit. The clinical record failed to evidence the staff of the ECF were trained to the specific needs of this patient. 2. On June 14, 2012, at 10:20 AM, employee A indicated the patient was assessed and identified as unstable on March 27, 2012, due to a fractured pelvis, infections, and was a nursing home patient. She indicated the patient received peritoneal dialysis per the ECF staff in the facility in which she resided. 3. On June 15, 2012, at 10:35 AM, employee F indicated the patient had been in 3 different nursing homes since March 27, 2012. 4. On June 15, 2012, at 10:45 AM, employee A indicated the dialysis facility did not have evidence the staff of the current extended care facility were trained by the dialysis staff to the specific dialysis needs of this patient. 		<p>dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V, effective administration of erythropoiesis-stimulating agents (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in the patient's care plan, how to detect, report, and manage potential dialysis complications, availability of support resources and how to access and use resources, how to self-monitor health status and record and report health status information, how to handle medical and non-medical emergencies, infection control precautions, proper waste storage and disposal procedures by 7/24/12 by a certified nephrology WellBound registered nurse or the Clinical Nurse Manager. Acknowledgement of retraining documentation will be stored in the patient medical record. Monitoring of the patient medical records for the signed training acknowledgement will be done after all training done in ECF for their staff to care for home dialysis patients of the facility by the Clinical Nurse Manager. To prevent recurrence, this will be audited as part of the regularly scheduled chart audits (see Exhibit B) and reported on at the QAPI meetings.</p>		

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V0586	<p>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;</p> <p>Based on clinical record review and interview, the facility failed to ensure documentation was in the medical record that the caregivers of the extended care facility who completed the peritoneal dialysis received training and demonstrated adequate comprehension of the training for 1 of 2 clinical records reviewed of patients who resided in an extended care facility with the potential to effect all 4 dialysis patients that reside in an extended care facility. (Patient 6)</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Clinical record # 6, start of care 6/11/08, evidenced the patient resided in an ECF and the facility staff were completing the patient's peritoneal dialysis daily beginning May 16 through June 15, 2012, date of survey exit. The clinical record failed to evidence the staff of the ECF were trained to the specific needs of this patient. 2. On June 14, 2012, at 10:20 AM, employee A indicated the patient was 	V0586	<p>494.100(b)(1) H-PT/CAREGIVER DEMO COMPREHEND TRAINING 1-4. Documentation will be in the medical record that the patient, the caregiver or both received and demonstrated adequate comprehension of training by 7/24/12. Monitoring of the patient medical records for the signed training acknowledgement will be done after all training done in ECF for their staff to care for home dialysis patients of the facility by the Clinical Nurse Manager. To prevent recurrence, this will be audited as part of the regularly scheduled chart audits (see Exhibit B) and reported on at the QAPI meetings.</p>	07/24/2012			

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	<p>assessed and identified as unstable on March 27, 2012, due to a fractured pelvis, infections, and was a nursing home patient. She indicated the patient received peritoneal dialysis per the ECF staff in the facility in which she resided.</p> <p>3. On June 15, 2012, at 10:35 AM, employee F indicated the patient had been in 3 different nursing homes since March 27, 2012.</p> <p>4. On June 15, 2012, at 10:45 AM, employee A indicated the dialysis facility did not have evidence the staff of the current extended care facility were trained by the dialysis staff to the specific dialysis needs of this patient.</p>				

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V0726	<p>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.</p> <p>Based on clinical record and policy review, administrative document log review, and interview, the facility failed to ensure the staff administered and documented accurately the administration of medications per facility policy and procedure for 1 of 1 facility surveyed with the potential to effect all 48 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The facility policy titled "Medication Administration / Dispense and Inventory Log", revision date 7/2/08, stated, "Document all medication administered or dispensed on corresponding form. All medications administered by a MA [medical assistant] must be cosigned by a RN (registered nurse)." 2. A review of the Medication Log, titled as a log for Epogen with the strength 20,000 units per milliliter, with multiple patient names on the facility log, 	V0726	<p>494.170 MR-COMPLETE, ACCURATE, ACCESSIBLE 1, 4. All medications administered by the MA will be cosigned by a RN on the Medication Administration/Dispense and Inventory Log by 6/26/12 per facility policy. Auditing of the Inventory Log for completeness will be done by the Clinical Nurse Manager or assigned Charge Nurse daily for 1 month then weekly to monitor compliance to the facility policy. (see Exhibit C) This will be reported on at the monthly QAPI meetings. 2, 3. All medications administered by the MA will be documented as given by the MA on the visit log in the patient medical record by 6/26/12. Auditing of the documentation on the visit log in the patient medical record will be done by the Clinical Nurse Manager or assigned Charge Nurse daily for one month, then weekly thereafter to monitor compliance of the accuracy of medication administration. (see Exhibit C) Audit results will be reviewed at the monthly QAPI</p>	06/26/2012

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	<p>evidenced employee D, a medical assistant, administered 9000 units to patient 3 on March 19, 2012, and 10,000 units to patient 6 on June 7, 2012. The entries on the log that were administered by employee D failed to be cosigned by a registered nurse or a physician.</p> <p>A. Clinical record 3 failed to evidence documentation by employee D the administration of Epogen on March 19, 2012.</p> <p>B. Clinical record 6 failed to evidence documentation by employee D the administration of Epogen on June 7, 2012.</p> <p>3. On June 14, 2012, at 2:40 PM, employee D, a medical assistant, indicated she administered vaccines and medications including Epogen to the dialysis patients and that she does not document in the patient's medical record. She indicated she documents the administration only on the medication log with the patients name, the dose administered, expiration date and lot number of the drug, and her initials on the entry. She indicated the registered nurses were to document the medication or vaccine was administered in the patient's clinical record.</p>		meetings for compliance to facility policy.		

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	<p>4. On June 14, 2012, at 3:06 PM, employee A indicated employee D was administering Epogen and vaccines to patients under the direction of the registered nurse. She indicated the registered nurses tell employee D what medication and vaccine to give and the dose. Then employee D obtains the medication, administers it, and then was to document on the medication log that corresponds to the medication that was administered. She indicated the registered nurses do not cosign the medications administered by employee D but do document in the medical record that the medication and vaccine was administered.</p>			