

**STATE OF CONNECTICUT  
DEPARTMENT OF PUBLIC HEALTH  
FACILITY LICENSING AND INVESTIGATIONS SECTION**

IN RE: DVA Healthcare Renal Care, Inc. of Denver, CO d/b/a  
Greater Waterbury Dialysis  
209 Highland Avenue  
Waterbury, CT 06708

**CONSENT ORDER**

WHEREAS, DVA Healthcare Renal Care, Inc. of Denver, CO (“Licensee”), has been issued License No. 0250 to operate an Outpatient Dialysis Unit known as Greater Waterbury Dialysis, (“Facility”) pursuant to Connecticut General Statutes section 19a-490 by the Connecticut Department of Public Health (“Department”); and,

WHEREAS, the Facility Licensing and Investigations Section (“FLIS”) of the Department conducted unannounced inspections on various dates commencing on May 18, 2015 and concluding on September 16, 2015; and,

WHEREAS, the Department, during the course of the aforementioned inspections identified violations of the Connecticut General Statutes and/or Regulations of Connecticut State Agencies in violation letters dated June 10, 2015, July 10, 2015 and October 9, 2015 (Exhibits A, B and C, copies attached); and,

WHEREAS, an office conference regarding the June 10, 2015 violation letter was held between the Department and the Licensee on June 30, 2015; and,

WHEREAS, the Licensee, without admitting any wrongdoing, is willing to enter into this Consent Order and agrees to the conditions set forth herein.

NOW THEREFORE, the FLIS of the Department acting herein and through Barbara Cass, its Section Chief, and the Licensee, acting herein and through Brian Karstetter, its Regional Director, ("parties") agree as follows:

1. The Licensee shall, within ten (10) days of the execution of this Consent Order, enter into a contract with an Environmental Consulting Firm or professional(s) ("ECF") that has expertise in life safety code issues involving an end stage renal dialysis health care setting. The ECF shall be approved by the Department prior to execution of the contract between the Licensee and the ECF.
2. The ECF shall conduct onsite reviews of the items specified in paragraph 4 of the Consent Order. The ECF team shall consist of credentialed professional(s) necessary to address the issues identified in Exhibits A, B and C of this Consent Order.
3. The ECF and the Licensee shall enter into a written contract that includes the following requirements of this Consent Order:
  - a. Timeframes for the initial evaluation; and,
  - b. The timeframes for the analysis and development of recommendations.
4. The initial onsite review shall be conducted within thirty (30) days of the execution of the contract with the ECF and shall include the following:
  - a. Evaluation of Facility processes for assessing water and equipment used for dialysis to ensure that such meets the water and dialysate quality standards;
  - b. Evaluation of the physical plant and compliance with life safety code standards including review of any existing proposed renovation/improvement plans;
  - c. Evaluation of the Facility generator with a focus on installation and maintenance in accordance with state and federal standards;
  - d. Assessment of ambient temperatures;
  - e. Evaluation of the preventative maintenance program that includes, but is not limited to, home dialysis machines, dialysis machines and ancillary equipment; and,
  - f. Emergency preparedness procedures to include, but not be limited to, fire response procedures.
5. The ECF shall have thirty (30) days after the completion of the initial onsite review, to develop a report(s) and provide copies of the report to the Licensee and Department.

Neither party shall be provided with the opportunity to review the report prior to its release. Both parties shall receive copies of the report(s) simultaneously. The report(s) shall identify methods utilized for the analysis, areas reviewed and process, and findings and recommendations. If the Licensee disagrees with any ECF findings or recommendations, the Licensee, the ECF and the Department shall meet to discuss issues. The Licensee shall have the right to present information related to the Licensee's areas of disagreement.

6. The Department shall have the final determination to accept or reject the ECF recommendations should the ECF and the Facility not be able to reach a mutual agreement.
7. Upon approval by the Department of the recommendations by the ECF, the Licensee shall provide the Department with a proposed timeframe for implementation of the ECF recommendations and any plans for facility renovation and improvements, if applicable, within thirty (30) days of receipt of the report(s). The timeframes shall be subject to approval by the Department and shall become operative upon the Department's approval. All recommendations shall be implemented in accordance with the Department's approved timeframe.
8. Any records maintained in accordance with any state or federal law or regulation or as required by this Consent Order shall be made available to the Department upon request.
9. The ECF shall re-evaluate the Licensee at three (3) months following the Department's approval of the time frames for implementation of the ECF's recommendations, as set forth in paragraph 7, or at such later date as may be recommended by the ECF and approved by the Department to assess the Licensee's implementation of such recommendations. Upon conclusion of said reviews, the ECF shall provide the Department with a comprehensive report of said assessment.
10. Within sixty (60) days of the execution of this Consent Order and in consultation with the ECF, the Licensee shall review and revise, as applicable, all policies and procedures regarding:
  - a. Processes for assessing water and equipment used for dialysis to ensure that such meets the water and dialysate quality standards;
  - a. Physical plant and compliance with life safety code standards;

- b. Generator maintenance;
  - c. Ambient temperatures;
  - d. Testing of water used for dialysis procedures;
  - e. Preventative maintenance program for all equipment, as applicable;
  - f. Emergency preparedness procedures to include, but not be limited to, fire response procedures;
  - g. Interdisciplinary patient assessment;
  - h. Comprehensive treatment planning;
  - i. Assessment of central venous catheters;
  - j. Assessment of patients who are experiencing a change in condition;
  - k. Communication to the governing body;
  - l. All policies and procedures regarding infection control;
  - m. Sufficient equipment and supplies are available, and
  - n. All Registered Nurses and Licensed Practical Nurses are competency tested regarding care of the patient in the end stage renal dialysis setting.
11. Within twenty-one (21) days of the revisions to the policies and procedures, the License shall provide in-service education to all applicable staff regarding all policies and procedures as identified in paragraph 10 of this Consent Order and shall be repeated, as applicable, at the time of employment and yearly thereafter to staff.
12. Documentation of in-service education shall be maintained for review by the Department for a period of three (3) years.
13. Within thirty (30) days of the execution of this Consent Order the Licensee shall ensure that the Corporation's Regional Nurse (CRN) conducts weekly visits for twelve (12) weeks and monthly rounds thereafter for the tenure of this Consent Order. The visits shall include:
- a. A review of staffing to verify that staffing is maintained in accordance with state and federal laws and regulations;
  - b. Surveillance monitoring to verify that infection control principles are maintained and in accordance with standards of care;
  - c. Assessment of water testing for use in the dialysis procedures to verify that the testing is conducted in accordance with the manufacturers;

- d. Verifying that the Licensee employs or contracts with sufficient infection control staff who are credentialed in infection control to track and monitor infections within the Facility;
  - e. Assessing the implementation of infection control techniques of staff providing direct care; and
  - f. Reviewing with the Facility Administrator and Medical Director, all new admissions to assess current infections and/or status of past infections.
14. Should the CRN identify any circumstances that the CRN believes constitute deviations from the standard of care and/or compliance with state and federal laws and regulations, including, but not limited to the provision identified in paragraph thirteen (13), s/he shall conduct remediation and training specific to the issue. All such incidents of remediation and training shall be documented and maintained on file for a period of three (3) years and shall be available to the Department upon request.
15. The CRN shall submit a monthly written report identifying the Facility's initiatives to comply with applicable federal and state statutes.
16. Effective upon the execution of this Consent Order, the Licensee, through its Governing Body and Facility Administrator shall ensure continued substantial compliance with the following:
- a. Sufficient nursing personnel are available to meet the needs of the patients;
  - b. Patient dialysis treatments, therapies and medications are administered as prescribed by the physician and in accordance with each patient's comprehensive care plan;
  - c. Patient assessments are performed in a timely manner and accurately reflect the condition of the patient;
  - d. Each patient care plan is reviewed and revised to reflect the individual patient's problems, needs and goals, based upon the patient assessment and in accordance with applicable federal and state laws and regulations;
  - e. Each patient's nutritional and fluid management needs are assessed and monitored in accordance with his/her individual needs and plan of care;
  - f. The personal physician or covering physician is notified in a timely manner of any significant changes in patient condition; and,

- g. Necessary supervision is provided to prevent accidents.
17. At the time of the signing of this Consent Order, the Licensee shall designate an individual within the Facility to monitor the requirements of this Consent Order. The name of the designated individual shall be provided to the Department with the transmittal of the signed Consent Order.
18. The Licensee shall continue its Quality Assessment and Performance Improvement Program ("QAPI") consisting of, at least, the Facility Administrator and Medical Director to review patient care issues including those identified in the June 10, 2015 and October 9, 2015 violation letters. The Committee shall meet at least once every month to review all reports or complaints relating to patient care and compliance with federal state laws and regulations. The activities of the Quality Assurance Performance Improvement Committee shall include, but not be limited to, determination and adoption of new policies to be implemented by the Licensee's staff to improve patient care practices. In addition, this Committee shall review and revise, as applicable infection control policies and procedures and monitor their implementation. The Committee shall implement a quality assurance program that will measure, track and report on compliance with the requirements of this Consent Agreement. The Committee shall measure and track the implementation of any changes in the Licensee's policies, procedures, and allocation of resources recommended by the Committee to determine compliance with and effectiveness of such changes. A record of quality assurance meetings and subject matter discussed will be documented and available for review by the Department. Minutes of all such meetings shall be maintained at the facility for a minimum period of five (5) years.
19. At the time of signing this Consent Order, the Licensee shall pay a monetary penalty to the Department in the amount of Five Thousand (\$5,000.00) dollars by money order or bank check payable to the Treasurer of the State of Connecticut. The money penalty and any reports required by this document shall be directed to:

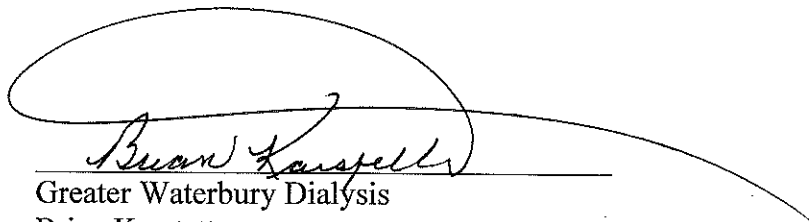
Cheryl Davis, R.N., B.S.N.  
Supervising Nurse Consultant  
Facility Licensing and Investigations Section  
Department of Public Health  
410 Capitol Avenue, P.O. Box 340308, MS #12HSR  
Hartford, CT 06134-0308

20. All parties agree that this Consent Order is an Order of the Department with all of the rights and obligations pertaining thereto and attendant thereon. Nothing herein shall be construed as limiting the Department's available legal remedies against the Licensee for violations of the Consent Order or of any other statutory or regulatory requirements, which may be sought in lieu of or in addition to the methods of relief listed above, including all options for the issuance of citations, the imposition of civil penalties calculated and assessed in accordance with Section 19a-524 et seq. of the General Statutes, or any other administrative and judicial relief provided by law. This Consent Order may be admitted by the Department as evidence in any proceeding between the Department and the Licensee in which compliance with its terms is at issue. The Licensee retains all of its rights under applicable law. The allegations and findings contained in Exhibits A and B shall be deemed true in any subsequent proceeding in which the licensee's compliance with the Consent Order is at issue or the licensee's compliance with Connecticut statutes and regulations and/or with Federal statutes and regulations is at issue.
21. The Licensee agrees that this Consent Order will be reported consistent with federal and state law and regulations and consistent with Department policy. In addition, the Licensee agrees that this Consent Order will be posted on the Department's website.
22. The Licensee agrees that this Consent Order does not limit any other agency or entity in any manner including but not limited to any actions taken in response to the factual basis of this Consent Order.
23. The terms of this Consent Order shall remain in effect for a period of two (2) years from the effective date of this Consent Order unless otherwise specified in this Consent Order.
24. The Licensee agrees that this Consent Order and the terms set forth herein are not subject to reconsideration, collateral attack or judicial review under any form or in any forum including any right to review under the Uniform Administrative Procedure Act, Chapter 368a of the Statutes, Regulations that exists at the time the agreement is executed or may become available in the future, provided that this stipulation shall not deprive the Licensee of any other rights that it may have under the laws of the State of Connecticut or of the United States.

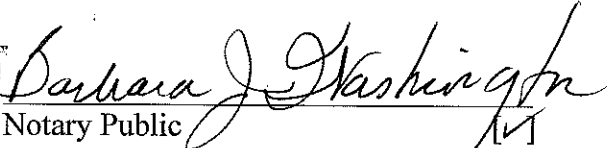
25. Should the Licensee not be able to maintain substantial compliance with the requirements of the Consent Order the Department retains the right to issue charges including those identified in the June 10, 2015 and October 9, 2015 violation letters referenced in this Consent Order.
26. The execution of this document has no bearing on any criminal liability without the written consent of the Director of the MFCU or the Bureau Chief of the Department of Criminal Justice's Statewide Prosecution Bureau.
27. The Licensee consulted with its attorney prior to the execution of this Consent Order.



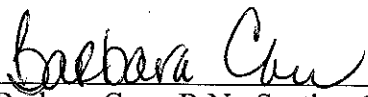
WITNESS WHEREOF, the parties hereto have caused this Consent Order to be executed by their respective officers and officials, which Consent Order is to be effective as of the later of the two dates noted below.

  
Greater Waterbury Dialysis  
Brian Karstetter  
Regional Director

On this 9th day of March, 2016, before me, personally appeared Brian Karstetter who acknowledged himself to be the Regional Director of Greater Waterbury Dialysis and that as such Regional Director being authorized so to do, executed the foregoing instrument for the purposes therein contained, by signing the name of the Licensee by himself as Regional Director.

My Commission Expires: My Commission Expires June 30, 2019  
(If Notary Public)   
Notary Public  
Commissioner of the Superior Court [ ]

STATE OF CONNECTICUT,  
DEPARTMENT OF PUBLIC HEALTH

By:   
Barbara Cass, R.N., Section Chief  
Facility Licensing and Investigations Section

March 10th, 2016



# STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Exhibit A

June 10, 2015

Shawana Rivero, Administrator  
Greater Waterbury Dialysis  
209 Highland Avenue  
Waterbury, CT 06708

Dear Ms. Rivero:

Unannounced visits were made to Greater Waterbury Dialysis on May 18, 19 and 20, 2015 by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting a licensure renewal and certification inspection.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

An office conference has been scheduled for June 30, 2015 at 10:00 in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish to retain legal representation, your attorney may accompany you to this meeting.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by June 24, 2015 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

Please prepare a written Plan of Correction for the above mentioned violations to be presented at this conference.

Each violation must be addressed with a prospective Plan of Correction which includes the following components:

1. Measures to prevent the recurrence of the identified violation, (e.g., policy/procedure, inservice program, repairs, etc.).
2. Date corrective measure will be effected.
3. Identify the staff member, by title, who has been designated the responsibility for monitoring the individual plan of correction submitted for each violation.

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.



Phone: (860) 509-7400  
Telephone Device for the Deaf (860) 509-7191  
410 Capitol Avenue - MS # 12HSR  
P.O. Box 340308 Hartford, CT 06134  
An Equal Opportunity Employer

DATES OF VISIT: May 18, 19 and 20, 2015

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT  
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES  
WERE IDENTIFIED

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Handwritten signature of Cheryl Davis, R.N., B.S.N. The signature is written in cursive and includes the initials "SNC" to the right of the name.

Cheryl Davis, R.N., B.S.N.

Supervising Nurse Consultant

Facility Licensing and Investigations Section

CAD:lsf

DATES OF VISIT: May 18, 19 and 20, 2015

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The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D55a (c) Governing Body (1)(A) and/or (B)(i) and/or (d) Administrator/Director (2) and/or (g) Nurse Manager (3) and/or (4).

1. Based on observation and policy review the facility failed to ensure that staff and/or patients' and/or volunteers followed the facility policy for handwashing between tasks. The findings include the following:
  - a. On 05/18/2015 at 11:18 AM the patient at station #5 was observed to touch his/her access site without gloves on. The patient proceeded to the sink to wet a paper towel, wiped the access site with the paper towel and left the unit without the benefit of hand hygiene and/or without staff reminders to perform hand hygiene.
  - b. On 05/18/2015 at 2:09 PM, LPN #1 was observed with gloves on stripping a machine, at station #30 and with the same gloves touched another machine then removed gloves and performed hand hygiene.
  - c. On 05/20/2015 at 10:48 AM, Patient #11 was observed holding his/her access site and walking toward the scale when RN#2 requested that the patient to sit back down as he/she couldn't "walk over there holding" (his/her) site. Patient #11 returned to Station #26, discarded the pressure gauze, removed his/her gloves and proceeded to exit the unit without performing hand hygiene and/or without the benefit of staff reminders to perform hand hygiene.
  - d. On 05/20/2015 at 11:10 AM, Patient #12 was observed walking toward the scale. Patient #12 discarded his/her glove, weighed him/herself and pressed the control panel without the benefit of hand hygiene. Patient #12 called out his/her weight to RN#2 then exited the unit without performing hand hygiene and/or staff reminders to perform hand hygiene.
  - e. On 05/20/2015 at 11:07 AM, a facility volunteer without glove was observed to assist a patient into the unit, assisted the patient to the chair, placed the patient's personal items on the counter then went to the nursing station without the benefit of performing hand hygiene.

Review of the facility's Infection Control Policy identified that hand hygiene is to be performed upon entering the facility, prior to gloving, after removal of gloves, after contamination with blood or other infectious material, after patient and dialysis delivery system contact, between patients even if the contact is casual, before touching clean areas such as supplies and before leaving the patient care area.

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2. Based on observation, interview and policy review the facility failed to ensure that contaminated surfaces, medical devices, and equipment were cleaned and disinfected between patients'. The findings include the following:

- a. On 05/18/2015 at 11:05 AM the plastic container at the patient's bedside that contained tape was not wiped down prior to being returned to the counter.
- b. On 5/18/14 at 11:07 AM LPN#1 was observed cleaning the chair at Station #2. LPN#1 proceeded to wipe the pillow and placed the pillow on an unclean surface (counter). Subsequently, at 11:15 AM, LPN#1 retrieved the pillow from the counter and without cleaning the pillow, applied a pillowcase and placed it on the chair for the next patient.
- c. On 05/18/2015 at 11:17 AM clean pillows and chair pads at station 24 were observed to be placed on the counter behind the station where patient personal items were stored.
- d. Observations on 5/19/15 during the period of 10:15 AM through 10:30 AM, CCHT #2 cleaned the pillows at Station #29, 30 and 27, then placed the pillows on the unclean counter behind the chairs.
- e. On 05/19/2015 at 10:40 AM, RN #1 was observed to angle a machine away from an occupied chair to clean the machine while the patient remained in the chair with his/her site accessed (needles in place). The RN proceeded to the chairside to remove the needles and in the process came in contact with the "clean" machine. The nurse failed to exercise extreme caution to prevent cross contamination.

Interview with the Facility Administrator on 5/19/15 at 10:35 AM identified that although the counters are wiped each morning before treatments begin and again at the end of the day when treatments are over, if staff were going to place reusable items on the counter between patients they should clean the counter between patients.

- f. On 5/20/15 at 10:40 AM, while cleaning station #29 between patients, CCHT#1 was observed to remove the cushion from the chair, wiped it and placed on the soiled counter.
- g. On 5/20 15 at 10:51 AM, RN#2 was observed cleaning station #26. RN#2 proceeded to wipe the pillow and place it on the unclean counter where the previous patient's personal items were stored.

During an interview on 5/20/15 at 2:55 PM, the FA identified that staff were reeducated on the facility's infection control practices, which included to avoid placing disinfected items on a dirty surface.

Review of the facility's Infection Control policy identified that equipment including the dialysis delivery system, interior and exterior of the prime container, the dialysis chairs and side tables including opening the chair to reach crevices, blood pressure equipment, TV's, IV poles as well as all work surfaces will be wiped with a bleach solution before being used by another patient.

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3. \*Based on observation, interview and policy review the facility failed to ensure that testing for free chlorine, chloramine, or total chlorine was performed per the manufacturer's directions for use (DFU). The finding includes the following:
- a. On 5/18/15 at 1:05 PM, CCHT#1 was observed completing water testing. CCHT#1 collected 100 milliliters (ml's) of water from the reverse osmosis (RO) loop, removed an ultra Low total chlorine test strip from the foil, dipped the test strip into the water, moved the test strip back and forth in the water for 60 seconds, removed the test strip from the water, folded the strip and compared it the strip on the reagent pad. CCHT#1 immediately read the results of the test and stated that the results were less than 0.1 ppm/mg. without waiting for the test strip to develop ( 20 seconds per DFU). Subsequent to surveyor inquiry CCHT#1 stated that she usually waited a few seconds before reading results.

CCHT#1 brought the strip and the reagent pad to LPN#3 to verify that the results were less than 0.1 ppm/mg, as the results appeared to be between 0.05 and 0.1 ppm/mg. Rather than document the actual quantitative value of the results, CCHT#1 documented that the results were less than 0.1.

Interview with the RN#5 on 5/20/15 at 1:30 PM identified that staff is expected to document the actual number that correlates to color on the reagent pad. Subsequent to this observation, staff were re-educated on the procedure to test water.

Review of the manufacturer's instruction for use of the Ultra Low test strips, with CCHT#1, directed to wait 20 seconds for the test strip to develop and after the 20 second wait period, compare the strip color to the color chart to determine the total chorine level in the sample and document the results.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D55a (c) Governing Body (1)(A) and/or (B)(i) and/or (d) Administrator/Director (2) and/or (l) General (6).

4. \*Based on observation during tour on 05/19/15 at 9:00 AM while accompanied by the Regional, Bio-Medical Technician and the Bio-Medical Technician, the facility failed to maintain a safe environment. The findings include the following:
- a. The surveyors, while accompanied by the Regional, Bio-Medical Technician and the Bio-Medical Technician observed that the connectors and connections throughout the clinic for the individual supplies for each, patient dialysis machine where laden with oxidation, staining and soils consistent with leaks and spills from the central water delivery system.
  - b. Tour of the unit on 5/1/15 at 9:00 AM identified that clean supplies were being stored in the ante room of the isolation room. Interview with staff indicated the supplies had been moved there secondary to the leak in the supply room.

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- c. The surveyors, while accompanied by the Regional, Bio-Medical Technician and the Bio-Medical Technician observed that the patient, chair-side, carts located throughout the treatment floor and the Isolation Room were corroded, rusted and otherwise not being maintained in a clean or safe manner.
- d. The surveyor, while accompanied by the Regional, Bio-Medical Technician observed that an electric, portable, space heater was located in the (former) Re-Use Storage Closet; i.e. portable heating device not prohibited in facility.
- e. The surveyors, while accompanied by the Regional, Bio-Medical Technician and the Bio-Medical Technician observed that an electric, portable, space heater was located in the Staff Break Room on the Lower Level; i.e. portable heating device not prohibited in facility.
- f. The surveyor, while accompanied by the Regional, Bio-Medical Technician observed that at least 16 (sixteen) cans of expired, Ensure and Glucerna food supplement were located in the (former) Re-Use Storage Closet; i.e. food stuffs expired for use in January 2015.
- g. The surveyors, while accompanied by the Regional, Bio-Medical Technician and the Bio-Medical Technician observed that the facility's rain gutters, downspouts, leaders, drains and other related equipment were damaged, not being maintained and otherwise no longer shedding rain and moisture away from the building during inclement weather; i.e. holes and voids can be seen in gutters, rain flowing over top of gutters.
- h. The surveyors were not provided with documentation from the Regional, Bio-Medical Technician or the Bio-Medical Technician to indicate that the facility has developed, maintained or implemented a maintenance program that ensures that the facility's rain gutters, downspouts, leaders, drains and other related equipment are free from damage and conditions that prevent the shedding of rain and moisture away from the building during inclement weather; i.e. current conditions allow for roof damage and potential building evacuation.
- i. The surveyors were not provided with documentation from the Regional, Bio-Medical Technician or the Bio-Medical Technician to indicate that the facility has developed, maintained or implemented a maintenance program or environmental care rounds system that ensures that the facility's safety, comfort and environmental needs are identified and addressed.
- j. The surveyors, while accompanied by the Regional, Bio-Medical Technician and the Bio-Medical Technician observed that the patient chairs located throughout the PD Department on the Lower Level were corroded, rusted and otherwise not being maintained in a clean or safe manner.
- k. The surveyors, while accompanied by the Regional, Bio-Medical Technician and the Bio-Medical Technician observed that the wall mounted, Clean Sink located in the PD Department on the Lower Level was loose where it attached to the wall and otherwise not being maintained in a clean or safe manner.
- l. The surveyors were not provided with documentation from the Regional, Bio-Medical Technician or the Bio-Medical Technician to indicate that the battery(s) in the fire alarm

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- control panel (s) have been replaced, as indicated on the 01/19/15 fire alarm inspection report by FireTech as requiring attention.
- m. The surveyors were not provided with documentation from the Regional, Bio-Medical Technician or the Bio-Medical Technician to indicate that the facility smoke dampers located throughout the facility were inspected at least annually.
  - n. The surveyors were not provided with documentation from the Regional, Bio-Medical Technician or the Bio-Medical Technician to indicate that the facility electrical receptacles located in patient areas were being tested & inspected at least annually.
  - o. The surveyors, while accompanied by the Regional, Bio-Medical Technician and the Bio-Medical Technician observed that that soiled linen or trash collection receptacles exceeded 32 gal in capacity and not located in a room protected as a hazardous area when not attended; i.e. 55-gallon trash barrel located on treatment floor.
  - p. The surveyors, while accompanied by the Regional, Bio-Medical Technician and the Bio-Medical Technician observed that that ceiling tiles throughout the facility (warehouse-store room, storage room off treatment floor & treatment floor) were removed and not in place where ceilings were either damaged by roof failure or voids are being used to ventilate the ceiling space; i.e. roof damage occurred in February 2015 and not yet addressed.
  - q. The surveyors, while accompanied by the Regional, Bio-Medical Technician and the Bio-Medical Technician observed that plastic sheeting and temporary wall materials have been installed within the treatment floor that interfere with sprinkler head spray pattern discharge and required HVAC air exchange rates i.e. roof damage occurred in February 2015 and temporary measures still in place.
  - r. The surveyors, while accompanied by the Regional, Bio-Medical Technician and the Bio-Medical Technician observed that the facility roofing system that suffered failure in February 2015 has not been repaired, replaced or otherwise deemed suitable for continued use; i.e. Director of Operations reports roof not repaired, date of repair not available.
  - s. The surveyors, while accompanied by the Regional, Bio-Medical Technician and the Bio-Medical Technician observed that surge protectors were installed above the ceiling throughout the treatment floor and were being used as permanent wiring systems where hard-wired, receptacles should have been provided; i.e. the patient television set installation did not include proper electrical receptacles and power strips were ordered removed in the past.
  - t. The surveyors were not provided with documentation from the Regional, Bio-Medical Technician or the Facility Administrator to indicate that fire drills were conducted quarterly since November 2014.

Interview with the assistant FA on 5/19/15 at 2:45 PM indicated that environmental rounds had not been completed for a period of time and therefore were not included and/or identified in facility health report (FHR). Interview with the Facility Administrator on 05/20/2015 11:45 AM indicated that the last fire drill completed was



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in November 2014. The FA indicated that with the transition away from inventory clerk being responsible for the fire drills and the environmental rounds the facility was remiss in completing the tasks when the transition was made.

5. \*Based on observation during tour on 05/19/15 at 9:00 AM while accompanied by the Regional, Bio-Medical Technician and the Bio-Medical Technician, the facility failed to ensure that ancillary items, such as the emergency generator was installed and maintained in accordance with state, federal standards. The findings include the following:
- The surveyors, while accompanied by the Regional, Bio-Medical Technician and the Bio-Medical Technician observed that a color coding system for the facility electrical receptacles that are connected to the facility generator was not implemented or maintained; i.e. while staff believes all receptacles are connected to generator-not all receptacles are of the same color coding as required.
  - The surveyors were not provided with documentation from the Regional, Bio-Medical Technician or the Bio-Medical Technician to indicate that the generator was exercised at least once monthly, for a minimum of 30 minutes under operating temperature conditions or at not less than 30 percent of the EPS nameplate rating or loading that maintains the minimum exhaust gas temperatures as recommended by the manufacturer; i.e. generator failed load bank on 03/31/15 and never retested.
  - The surveyors were not provided with documentation from the Regional, Bio-Medical Technician or the Bio-Medical Technician to indicate that the repairs to the generator that were discovered on 03/31/15 by Kinsley Power Systems that prevented a load bank test to be conducted were repaired or addressed i.e. generator failed load bank on 03/31/15 and never repaired for retest.
  - The surveyors were not provided with documentation from the Regional, Bio-Medical Technician or the Bio-Medical Technician to indicate that the Nextstage/Baxter, Home Choice dialysis machine located in the PD Department-Lower Level , Exam Room #1 of the facility had electrical safety testing & inspection conducted on it prior to it being placed into service.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D55a (d) Administrator/Director (2).

6. Based on tour and interview the facility failed to ensure that a comfortable temperature within the facility was maintained. The finding includes the following:
- Tour of the unit on 5/18/15 accompanied by the Regional, Bio-Medical Technician and the Bio-Medical Technician observed that the air temperature throughout the treatment floor was not being maintained at a level that was comfortable for patients.
  - Interview with Patient #9 on 5/18/15 at 10:15 AM identified that it was cold on the treatment floor and numerous complaints to administration had been submitted.
  - Test of the ambient temperature of the dialysis unit on 5/19/15 at 2:00 PM identified the

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temperature of the entrance portion of the treatment floor registered 60 degree Fahrenheit and the back portion of the treatment floor registered 70 degrees.

- d. Interview with the Assistant Facility Administrator (AFA) and review of the grievance log on 5/20/15 at 2:00 PM identified that there had been several patient complaints related to the temperature of the unit. An entry dated 4/13/15 indicated that there was a patient complaint related to the unit temperature. The log failed to identify a documented resolution. The AFA stated that she met with the patient and indicated that although she did not check the temperature of the unit, she provided him/her a blanket in response to his/her complaint. The AFA stated that the policy was to maintain the temperature on the treatment floor between 72-76 degrees and that no tracking by the facility was completed (Public Health Code directs 70-76 degrees).

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D55a (d) Administrator/Director (2) and/or (e) Medical/Director (3)(A).

7. \*Based on clinical record review and policy review the facility failed to ensure that the physician's section of the comprehensive assessment was completed for eight (8) of ten (10) patients reviewed (Patients #1, 2, 4, 5, 7, 8, 9, 10 ) prior to the completion of the care plan. The findings include the following:
  - a. Review of Patient #1's clinical record identified that on 5/27/14 a 90 day care plan was completed. Review of the record failed to identify that a comprehensive physician's assessment was completed prior to the completion of the care plan on 5/27/14.
  - b. Review of Patient #2's clinical record indicated that a comprehensive assessment was completed on 4/3/15 related to a change of modality however the record failed to reflect the presence of a physician's comprehensive assessment.
  - c. Review of Patient #4's clinical record identified that a care plan dated 3/9/15 was completed for the patient's change of modality from peritoneal dialysis to incenter hemodialysis. Review of the record identified a physician's comprehensive assessment dated 2/23/15 which pertained to the patient's peritoneal dialysis however the record failed to identify that a comprehensive physician's assessment pertaining to the patient's hemodialysis was completed until 4/13/15, after the completion of the 3/9/15 care plan.
  - d. Review of Patient #5 clinical record indicated that on 5/15/14 an annual care plan was completed. Review of the record failed to reflect that a corresponding physician assessment was completed. The plan of care identified that the patient was unstable at that time. The clinical record indicated that a care plan and reassessment was completed on 7/14/14 however the record failed to reflect the presence of a physician's assessment.
  - e. Review of Patient #7's clinical record indicated that the plan of care was completed by the interdisciplinary team on 2/18/15, however the clinical record failed to reflect the presence of a physician assessment prior to the completion of the plan of care.
  - f. Review of Patient #8's clinical record identified that the patient was admitted on 1/16/15 with an initial comprehensive care plan dated 2/18/15. Review of the record identified

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that although a physician's progress note was completed in January 2015, the record failed to identify that the physician participated in the patient's comprehensive interdisciplinary assessment prior to the development of the 2/18/15 care plan.

- g. Review of Patient #9's clinical record indicated that a plan of care was completed on 10/1/14 by the interdisciplinary team however the record failed to reflect the presence of a physician assessment prior to the completion of the plan of care. The clinical record reflected that the physician completed an assessment (history and physical) on 10/14/14.
- h. Review of Patient #10's clinical record indicated that the patient was admitted to the unit in 8/2014. Review of the initial assessment and the 90 assessment failed to reflect that the physician had completed a comprehensive assessment.

Interview with the FA on 5/20/15 at 10:00 AM stated that a physician's H&P and/or monthly comprehensive visit note has served as the assessment for the patient's care plan if it completed prior to the care plan.

Review of the facility's policy identified, in part, that the Interdisciplinary Team (IDT) consists of a registered nurse, dietician, social worker and the physician treating the patient for ESRD. The IDT is responsible for providing each patient with an individualized and comprehensive assessment documenting his/her needs to assist in the creation of the plan of care.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D55a (d) Administrator/Director (2) and/or (g) Nurse Manager (3) and/or (4) and/or (h) Nursing Staff (4) and/or (j) Clinical Records (3).

- 8. Based on clinical record review and policy review for one of three ambulatory patients (Patient#2) the facility failed to ensure that blood pressures were monitored in accordance with facility policy. The finding includes the following:
  - a. Review of Patient #2's treatment flow sheets for the period of 4/1/15 through 5/20/15 identified that on eleven (11) occasions, staff failed to obtain a pre and/or post standing blood pressures on 4/1/15, 4/6/15, 4/10/15, 4/15/15, 4/24/15, 4/27/15, 5/6/15, 5/11/15, 5/13/15, 5/15/15 and 5/18/15. Review of the post-treatment assessment policy identified that the post treatment assessment aids in the evaluation of the effectiveness of the treatment plan and to assure that the patient's discharge status is stable prior to discharge.

According to facility policy, blood pressure readings obtained post-treatment were a part of the patient assessment that ensures the patient's stability.

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The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D55a (d) Administrator/Director (2) and/or (e) Medical Director (3)(A) and/or (g) Nurse Manager (3) and/or and/or (h) Nursing Staff (4) and/or (i) Additional Personnel (3)(D) and/or (4)(B) and/or (j) Clinical Records (3).

9. Based on a review of clinical records, interview, and policy review for two of ten unstable patients (#5 and #7) the facility failed to accurately determine stability status and/or ensure that assessments were completed in accordance with the facility policy. The findings include the following:
  - a. Patient #5 had an annual care plan dated 5/15/14 that identified the patient was unstable. Although review of the record indicated that the physician signed the plan of care, the record lacked a comprehensive assessment by the physician. Review of the record with the charge nurse on 5/20/15 indicated that a reassessment was not completed until 7/14/14 instead of monthly as required. In addition:  
Patient #5 had a physician's note dated 11/21/14 that identified the patient was discharged from the hospital after a 22 day stay for a right below the knee amputation. The clinical record indicated that the patient's albumin was 2.9 (goal > 4.0), hemoglobin was 7.9 (goal 10-12), and phosphorous was 2.6 (goal 3.0-5.5), all below the identified goals. Although the patient failed to meet the identified goals in the areas of fluid management, albumin, phosphorous, anemia, and ferritin, and had an extended hospitalization, the patient was designated as stable absent rationale for this designation.
  - b. Review of Patient #7's clinical record during the period of 12/14 through 2/15 noted the patient's Kt/v was 1.17 (goal >1.20) in December and January and 1.11 in February. The patient's albumin was 3.3 (goal >4.0) in December, 3.4 in January, and 3.2 in February. The patient had a hemoglobin of 9.1 (goal > 10.0) in December, 9.2 in January and 9.6 February. Patient #7 had a comprehensive assessment completed on 2/18/15 by the IDT that indicated the patient was stable absent a physician's assessment.

Review of the facility policy directed that a comprehensive reassessment should be completed at least monthly for unstable patients. The policy indicated a comprehensive reassessment of each patient and a revision of the plan of care must be conducted at least monthly for unstable patients including, but not limited to, patients with the following extended or frequent hospitalizations, deterioration in health status, significant change in psychosocial needs or concurrent poor nutritional status, unmanaged anemia and inadequate dialysis.

10. Based on clinical record review, interview and policy review, the facility failed to develop comprehensive care plans for two of ten clinical records reviewed (#2 and #7) to ensure the individualized needs of the patient were addressed. The findings include the following:
  - a. Patient #2 had a comprehensive assessment completed on 4/3/15 that identified the

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patient was designated as unstable. A comprehensive assessment completed by the physician on 4/27/15 indicated that the patient was unstable however the plan of care completed on 4/29/15 noted the patient was stable. The care plan identified that the patient's low albumin level could possibly be related to addiction behaviors, but failed to address the specific behaviors and/or addiction issues.

- b. Patient #7 had a comprehensive assessment completed on 2/18/15 that identified a psychosocial problem related to the deterioration of the patient's mental and functional status however lacked interventions to assist the patient to achieve the identified goal.

Review of the facility's Patient Assessment and Plan of Care Policy identified, in part, that a comprehensive assessment will be used to develop the patient's treatment plan and expectations of care. The policy further identified that the interdisciplinary team will develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D55a (c) Governing Body (1)(A) and/or (B)(i) and/or (d) Administrator/Director (2).

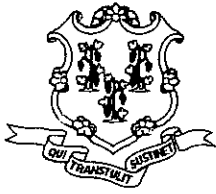
11. Based on a tour of the facility, review of facility documentation, and interview, the governing body failed to act promptly to address the identified environmental concerns. The finding includes the following:
  - a. Tour on 5/18/15 at 9:00 AM identified a sectioned off area of the treatment area secondary to a water leak that occurred on 2/7/2015 in the warehouse area. A second leak occurred on 2/23/2015 in the storeroom off of the patient floor, a leak was identified on 3/04/2015 from the treatment floor window area near the lab. Tour identified air scrubbers in the laboratory room, water room supply room, SW office and on the treatment floor. All supplies were removed from supply area and placed in the isolation anteroom room. Review of the governing body meeting minutes dated 3/5/15 noted that crews were onsite removing the snow and ice dams, on 3/11/15 the minutes reflected that a water leak in the lab area adjacent to the clinic floor was identified and DPH was notified. The minutes dated 3/17/15 indicated that air quality tests were completed in the SW office, RO room and storage room resulting in the placement of air scrubbers in the affected areas. The 3/23/15 minutes indicated that the team was working on scheduling roof/gutter evaluation. The 4/24/15 minutes indicated that the facility received notification that a OSHA complaint had been filed. The 5/6/15 meeting minutes indicated that the lab was being relocated to the dirty utility room. Interview with ROD and FA on 5/19/15 indicated that as of 5/19/15 the roof and/or gutters had not been evaluated for repair.

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The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D55a (d) Administrator/Director (2) and/or (g) Nurse Manager (3) and/or (4) and/or (5)(C) and/or (h) Nursing Staff (4).

12. Based on observation and interview the facility failed to ensure that a RN was present on the treatment floor at all times. The finding includes the following:
  - a. On 05/20/2015 at 9:00 AM upon entering the treatment area, five staff were present on the unit with 26 patients being dialyzed. The staff present were noted to be 2 LPN's and 3 CCHT's. At approximately 9:05 AM, the FA entered the unit and was made aware of the staffing level. Interview with the Charge Nurse on 5/20/15 at 9:10 AM, who was off the unit at the time, indicated that RN #2 had been left on the unit. Interview with the FA on 5/20/15 at 3:00 PM indicated that there should be a RN on the treatment floor at all times and all the staff on duty were reeducated on this issue on 5/20/15.



# STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Exhibit B

July 10, 2015

Ms. Shawana Rivero, , Administrator  
Greater Waterbury Dialysis  
209 Highland Avenue  
Waterbury, CT 06708

Dear Ms. Rivero:

An unannounced visit was made to Greater Waterbury Dialysis on 7/1/15 by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting a revisit pertaining to violation letter dated 6/10/15.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visit.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by July 24, 2015 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

Please address each violation with a prospective plan of correction which includes the following components within fourteen days of the date of this letter:

1. Measures to prevent the recurrence of the identified violation, (e.g., policy/procedure, inservice program, repairs, etc.).
2. Date corrective measure will be effected.
3. Identify the staff member, by title, who has been designated the responsibility for monitoring the individual plan of correction submitted for each violation.

We do not anticipate making any practitioner referrals at this time.

If there are any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Cheryl Davis, RN, BSN  
Supervising Nurse Consultant  
Facility Licensing and Investigations Section

CAD/



Phone: (860) 509-7400  
Telephone Device for the Deaf (860) 509-7191  
410 Capitol Avenue - MS # 12HSR  
P.O. Box 340308 Hartford, CT 06134  
An Equal Opportunity Employer

DATE OF VISIT: July 1, 2015

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT  
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES  
WERE IDENTIFIED

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D55a (c) Governing Body (1) (A) and/or (d) Administrator (2) and/or (g) Nurse Manager (3) and/or (l) General (6).

1. Based on observation, interview, and policy review, the facility failed to ensure that one patient's (#53) site was visible during treatment. The finding includes the following:
  - a. On 7/1/15 at 1:20 PM, Patient #53 was observed during dialysis treatment to have his/her entire body covered with blankets. Subsequent to inquiry, the blanket was removed to allow for visualization of the central venous catheter (CVC) site. Review of the care plan dated 5/20/15 failed to reflect a compliance issue related to the patient covering his/her site. Interview with the Assistant FA on 7/1/15 at 2:00 PM indicated that Patient #53 is always cold and wraps up in blankets. Interview with the FA on 7/1/15 at 3:30 PM indicated that the patient is always cold and was instructed earlier to remove the covering however the patient covered the site again. Review of the policy indicated that cannulation sites and blood tubing connections will remain visible throughout treatment.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D55a (c) Governing Body (1) (A) and/or (d) Administrator (2) and/or (g) Nurse Manager (3) and/or (5) and/or (l) General (6) and/or Public Act #05-66.

2. Based on a review of facility documentation the facility failed to ensure that staffing met the Regulations of Connecticut State Agencies. The finding includes the following:
  - a. Review of staffing for the period of 6/15/15 through 7/1/15 indicated that on two days the charge nurse was included in the staffing numbers and required to take a patient care assignment. The assignment sheet dated 6/19/15 indicated that at 2:00 PM to 4:00 PM the Charge Nurse covered a patient care assignment with a LPN and CCHT.
  - b. Review of the assignment sheet dated 6/20/15 with the FA indicated that the charge Nurse had a patient care assignment from 12:00 PM through 3:30 PM.

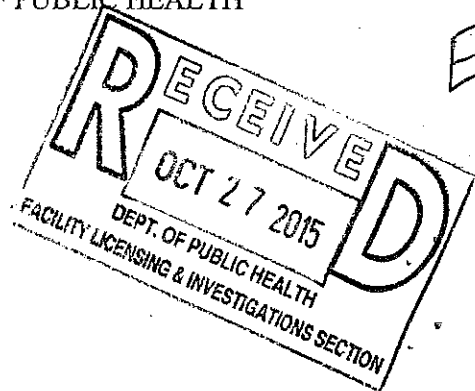




STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Exhibit C



October 9, 2015

Shawana Rivero, Administrator/  
Greater Waterbury Dialysis  
209 Highland Avenue  
Waterbury, CT

Dear Ms. Rivero:

An unannounced visit was made to Greater Waterbury Dialysis September 16, 2015 by a representative of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting a follow-up to the Plan of Correction for violation letter dated July 10, 2015.

Attached is the violation of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which was noted during the course of the visit.

A tele-conference has been scheduled for October 29, 2015 at 2:00PM. Please call me directly at 860-509-7436 and be prepared to discuss your plan of correction at this meeting. Should you wish to retain legal representation, your attorney may accompany you to this meeting.

You may wish to dispute the violation and you may be provided with the opportunity to be heard. If the violation is not responded to by October 23, 2015 or if a request for a meeting is not made by the stipulated date, the violation shall be deemed admitted.

Each violation must be addressed with a prospective Plan of Correction which includes the following components:

1. Measures to prevent the recurrence of the identified violation, (e.g., policy/procedure, inservice program, repairs, etc.).
2. Date corrective measure will be effected.
3. Identify the staff member, by title, who has been designated the responsibility for monitoring the individual plan of correction submitted for each violation.

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

*Cheryl Davis SNC*  
Cheryl Davis, RN, BSN, SNC  
Supervising Nurse Consultant  
Facility Licensing and Investigations Section

CAD:mb



DATE(S) OF VISIT: September 16, 2015

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT  
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES  
WERE IDENTIFIED

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D55a (c) Governing Body (1) (A) and/or (d) Administrator (2) and/or (g) Nurse Manager (3) and/or (5) and/or (1) General (6) and/or Connecticut General Statute Section 19a-269a.

1. \*Based on a review of facility documentation and interviews, the facility failed to ensure that staffing met the Regulations of Connecticut State Agencies. The findings include the following:
  - Review of the facility staffing for the period of 7/23/15 through 9/16/15 indicated that on eight (8) days the clinical coordinator/nurse manager and/or charge nurse was included in the staffing numbers and required to take a patient care assignment.
    - a. Review of the assignment sheet dated 7/25/15 identified that the clinical coordinator/nurse manager had a patient care assignment from 6:00 AM -9:00 AM.
    - b. Review of the assignment sheet dated 7/30/15 identified that the charge nurse, who was designated in the absence of the clinical coordinator, had a patient care assignment for all or part of the day.
    - c. Review of the assignment sheet dated 8/7/15 identified that the clinical coordinator/nurse manager had a patient care assignment from 1:30 PM to 9:00 PM.
    - d. Review of the assignment sheet dated 8/8/15 identified that the charge nurse, who was designated in the absence of the clinical coordinator had a patient care assignment for the day.
    - e. Review of the assignment sheet dated 8/10/15 identified that the charge nurse, who was designated in the absence of the clinical coordinator/nurse manager had a patient care assignment from 1:00 PM to 4:00 PM.
    - f. Review of the assignment sheet dated 8/11/15 identified that the clinical coordinator/ nurse manager had an assignment from 6:00 AM to 4:00 PM.
    - g. Review of the assignment sheet dated 8/12/15 identified that the clinical coordinator/nurse manager had an assignment for the day.
  - Interview with the Facility Administrator on 9/16/15 at 11:00 AM identified that the Nurse Manager/Clinical Coordinator should not be counted in the staffing pattern and a charge nurse is designated, as the nurse manager, in the absence of the nurse manager/clinical coordinator and the charge nurse should not have a patient assignment when he/she is designated in the absence of the nurse manager/clinical coordinator.