STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Deidre S. Gifford, MD, MPH
Acting Commissioner

Ned Lamont
Governor
Susan Bysiewicz
Lt. Governor

Healthcare Quality And Safety Branch

June 21, 2021

Mr. Lester Schindel, Administrator
Waterbury Hospital
64 Robbins St
Waterbury, CT 06721

Dear Mr. Schindel:

Unannounced visits were made to Waterbury Hospital on June 17, 2021 by a representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting a licensure inspection with additional information received through June 17, 2021.

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. The state violations cannot be edited by the provider in any way.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice.

The plan of correction is to be submitted to the Department by July 5, 2021

The plan of correction shall include:
(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;
(2) the date each such corrective measure or change by the institution is effective;
(3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and
(4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

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 5, 2021 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

Connecticut Department of Public Health

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Affirmative Action/Equal Opportunity Employer

DATE(S) OF VISIT: June 17, 2021

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

Please return your response to the Supervising Nurse Consultant via email at dph.flisadmin@ct.gov or right fax number 860-622-2655. Please direct your questions concerning the instructions contained in this letter to the Supervising Nurse Consultant at (860) 509-7400. Please do not send another copy via US mail.

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

Respectfully,

Susan Newton

Susan Newton, RN, BSSupervising Nurse Consultant
Facility Licensing and Investigations Section

SHN:mb

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1. Based on clinical record review and interview for one of three patients receiving hemodialysis (Patient #30) the facility failed to ensure that the patient's prescription was complete to include a prescribed blood rate. The finding included:
   a. Patient # 30's diagnoses included renal failure. Review of the patient's hemodialysis orders dated 6/16/2021 directed a one-time unscheduled hemodialysis treatment for ultrafiltration using a Revaclear dialyzer and an ultrafiltration goal of 4.5 liters however the order failed to include a prescribed Blood Flow Rate (BFR).
   Observation on 6/16/21 at 1:20 PM identified that the patient's treatment was initiated with a Revaclear 300 dialyzer, through the patient's Central Venous Catheter and the BFR set at 300 ml/min.
   Subsequent to surveyor inquiry, RN #8 acknowledged that physician's order should have specified the blood flow rate and although she did not contact the prescribing physician, it was a sequential treatment for ultrafiltration, it was common to run the BFR at 300 ml/min.
   In a subsequent interview on 6/17/21 at 11:30 AM, RN # 9 stated that all hemodialysis orders should include the blood flow rate and in the case that the blood flow rate is not included in the order, the nurse would contact the prescribing physician to obtain the rate with a telephone order, prior to starting the treatment.
   Interview with the clinical nurse specialist on 6/16/21 at 1:40 PM identified that the blood flow rate should have been included in the hemodialysis order and acknowledged that this practice would need to be addressed to tighten up the process. Review of the hemodialysis policy and procedures identified that hemodialysis is administered in accordance with the prescribed treatment that directs the type of dialyzer, the length of treatment, the access, the dialysate components and the dialysate (DFR) and blood flow rates (BFR).

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (a) Physical plant and/or (b) Administration (2) and/or (c) Medical Staff (2) and/or (e) Nursing Services (1) and/or (i) General (6) and/or (l) infection control (1).

2. Based on a tour of the operating room (OR), review of facility policies, observations and interviews the hospital failed to ensure proper hair coverage in restricted areas, failed to ensure surgical policies were complete and failed to ensure surgical/procedural equipment was maintained or properly stored. The finding includes:
   a. A tour of the main OR was conducted on 6/15/21 with Director #2. Observations on 6/15/21 at 10:00 AM identified Resident (R) #1 in OR #4 during a procedure. Although R #1 had donned a surgical mask. His full beard was not contained within the surgical mask. The observation further noted the anesthesia provider had donned a skull type surgical cap and approximately three inches of hair was exposed at the back of the head. An observation 0n 6/15/21 at 10:21 AM identified white beard covers and full blue head/side of face caps were available in the semi- restricted area of the OR.

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Observation on 6/15/21 at 10:30 AM noted MD #1 in the semi restricted area of the Reed OR area had donned a skull type surgical cap and approximately two and one half to three inches of hair was exposed at the back of the head/neck. MDF #1 subsequently donned a bouffant cap over the skull cap per the request of Director #1.
Interview with Director #2 on 6/15/21 at 10:01 AM noted that the hospital followed the standards of the Association of peri-Operative Registered Nurses (AORN) in the surgical areas. Director #2 noted that she believed the surgical attire policy called for all hair to be covered when in the semi- restricted and restricted surgical areas and did not know if the hospital had beard covers.
The hospital policy entitled surgical attire identified that skull caps may be worn if close to the totality of the hair is covered and only a limited amount of hair on the nape of the neck or sideburn remain uncovered. The policy further identified that disposable skull caps that do not cover close to the totality of the hair should not be worn, or if worn, covered with a disposable bouffant hair cap. The hospital policy did not direct staff for beard coverage, or the use of beard covers.
AORN copyright 2012- 2021 recommended to cover a beard when entering the restricted areas and while preparing items in the clean assembly of the sterile reprocessing area.
A tour of the Reed OR area was conducted with Director #2 on 6/15/21. Observation of OR #5 identified peeling, chipped paint on the base of the robotic monitor stand and a total of eight our rusted castors on the base of two intravenous poles.
Interview with Director #2 on 6/15/21 at 10:34 AM indicated that OR equipment was sanitized with the 3- minute contact germicidal. The peeling paint and rust rendered the equipment unable to be properly sanitized.
The hospital policy entitled Cleaning and Disinfection of Operating Room identified that ORs will be cleaned after every surgical procedure. The hospital policy entitled Cleaning and Disinfection of Non- Critical Equipment/Items in Healthcare directed to use an approved disinfectant to routinely cleanse non- critical items to include IV pumps.
A tour of the Reed pre/postoperative area was conducted with Director #2 on 6/15/21. Observations on 6/15/21 at 10:34 AM noted two older stretchers with multiple areas of ripped and peeling vinyl exposing the foam filling.
Interview with Director #2 on 6/15/21 at 10:34 AM indicated that OR equipment was sanitized with the 3- minute contact germicidal.
The hospital policy entitled Cleaning and Disinfection of Non- Critical Equipment/Items in Healthcare directed to use an approved disinfectant to routinely cleanse non- critical items to include stretchers.
A tour of the Gastroenterology department was conducted with Director #3 on 6/15/21. Observation of the scope storage closets on 6/15/21 at 11:40 AM identified two of the three closets with ten reprocessed scopes. The two storage closets lacked vents to ensure airflow.
Interview with Director #3 on 6/15/21 at 11:40 AM noted that the closets had been in use since the department moved to the new location.
The hospital policy entitled Gastroenterology Infection Prevention identified the scopes are hung in storage cabinets with adequate ventilation.

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3. Based on a tour of the Gastroenterology department, review of three operative/procedural medical records and interviews for one of three surgical patients (P #4), the hospital failed to ensure that the physician documented an immediate operative report. The finding includes:
   a. A tour of the gastroenterology department was conducted with Director #3 on 6/15/21. Observation on 6/15/21 at 11:18 AM noted that the department had three stretchers in the pre/postoperative care unit and all three stretchers were empty and clean. A review of electronic medical records (EMR) was conducted with RN #2 on 6/15/21 at 11:50 AM.
   P #4 was admitted for a colonoscopy by MD #2 on 6/15/21. The EMR identified that P #4's colonoscopy was performed by MD #2 and P #4 was discharged at 10:56 AM. The medical record lacked an immediate operative or operative report following the procedure and prior to the patient's discharge.
   P #5 was admitted for a colonoscopy by MD #2 on 6/15/21. The EMR identified that P #5's colonoscopy was performed by MD #2 and an immediate operative report for P #5 was observed in P #5's EMR.
   Interview with RN #2 on 6/15/21 at 11:50 AM noted that MD #2 usually dictated the immediate operative report in the procedure room and immediately after the patient's procedure.
   The hospital Rules and Regulations of the Medical Staff identified that for all out patients and in patients immediately following an invasive procedure or operation a brief operative/procedure report must be placed in the patient's hospital record and signed by the medical staff who performed the procedure.
   Public Act No. 15-11 Section 1. (1) (4) (c), An Act Concerning Persons Who Decontaminate Reusable Medical Equipment or Devices.
   Based on a tour of the Central Sterile and Gastroenterology Departments, review of personnel files and interviews for one of three reprocessing techs (Tech #1), the hospital failed to ensure that required yearly education was maintained. The finding includes:
   A tour of the Gastroenterology department was conducted on 6/15/21. The tour identified that Tech #1 was the lead technician in the department and reprocessed scopes using high level disinfection.
   Review of Tech #1's personnel record on 6/17/21 at 12:50 AM identified that Tech #1 completed 10 continuing education units (CEUs) for the 2019 year. The review further identified that CEUs for the year 2020 were not located in the personnel file.
   Interview with the Performance Specialist on 6/17/21 at 1:00 PM noted that the new educator informed Tech #1 that she was not required to maintain annual CEUs in her current role.
   According to Public Act No. 15-11 Section 1. (4) (c), "Central service technician" means a person who decontaminates, inspects, assembles, packages and sterilizes reusable medical instruments or devices in a health care facility. A central service technician shall complete a minimum of ten hours of continuing education annually. The continuing education shall be

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in areas related to the functions of the ventral service technician.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) (h) Dietary Services and/or (i) General (6) and/or (l) infection control (1).

4. Based on observation during a tour of the facility, review of facility policy and interview with facility staff, the facility failed to ensure that refrigerated food items were removed upon expiration. The Findings include:
   a. Observation during a tour of the facility's kitchen area, on 6/15/21 at 9:30AM, identified that refrigerator #3, in the main kitchen, contained 2 containers of chicken soup that were prepared on 6/10/21, however, only one of the labels specified the expiration date as 6/13/21. The other container did not have the expiration date written on the label.
   Review of facility policy for Food and Supply Storage identified that all food items in food preparation shall be stored in such a manner as to prevent contamination to maintain safety and wholesomeness of the food for human consumption. Unused portions of foods prepared on site, should be covered, labeled and dated. Further review of the policy identified that all sections of the Morrison orange label should be completed and that both reheated and not reheated, unused portions of foods are good for 3 days and that food past the use-by date or expiration date should be discarded.
   Interview with the Registered Dietician (RD) on 6/15/21 at 9:45AM, identified that the dietary managers should be monitoring the refrigerators daily in the morning and should immediately remove expired items. It was also identified by the Registered Dietician that prepared items in the refrigerator, should have the date of preparation and expiration dates written on the label.

The following are violations of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (g) Pharmacy and/or (i) General (6) and/or (l) infection control (1).

5. Based on observation during a tour of the facility, review of facility policy and interviews with facility staff, the facility failed to ensure that compounding pharmacy staff are following aseptic technique prior to compounding procedures and/or that the policy follows USP Chapter 797 standards for Compounding Sterile Products. The findings include:
   a. Observation of Pharmacy Technician #1 (PT#1) on 6/16/21 at 2:20PM, identified a donning PPE procedure in the Ante room. Although hand hygiene was performed correctly, PT#1 was observed drying their hands and arms starting from the fingertips up to the elbows, and then was observed immediately bringing the drying cloth back down to the fingertips.
   Review of PT#1's personnel file identified that h/she was trained on the Pharmacy Policy and Procedures for the Intravenous (IV) Room, however the date of the training was not indicated.
   Review of the Pharmacy Policy and Procedure Manual, Appendix B: Waterbury Hospital Intravenous (IV) Room Standard Operating Procedures (SOP) for the Non-Hazardous Drug Buffer Room and review of the United States Pharmacopeia Chapter 797 for Compounding

Sterile Preparations (USP 797), identified that after hand hygiene is complete, hands and arms are rinsed from fingertips to elbows, and then pat dry going from fingers to elbow. The IV SOP and the USP 797 standard do not identify that the drying towel should be brought back down to the fingers after drying the elbow. Further review of the IV SOP identified that competency in aseptic techniques of all compounding pharmacists and technicians is observed, evaluated and recorded during orientation and training and at least every 6 months or whenever unacceptable techniques are observed or detected. Review of the USP 797, identified that all compounding personnel must be visually observed initially and every 6 months while performing hand hygiene and garbing procedures and that the visual audit must be documented, and the documentation maintained to provide a record of personnel competency.

b. Review of the compounding pharmacy staff's gloved fingertip test results, identified that 4 of 4 sampled staff members, did not have 3 consecutive initial gloved fingertip tests performed. Further review of the gloved finger test results identified that the documentation did not include the media and components used manufacturer information, the starting temperature for each interval of incubation, and the identification of the observer and the person who reads and documents the results.
Review of the USP 797, identified that before being allowed to independently compound, all compounders must successfully complete an initial competency evaluation, including visual observation and gloved fingertip and thumb sampling on both hands, no fewer than 3 separate times. After the initial competency evaluation, compounding personnel must successfully complete gloved fingertip and thumb sampling at least every 6 months after completing the media-fill test. Results of the evaluation and corrective actions, in the event of failure, must be documented and the documentation maintained to provide a record and long-term assessment of personnel competency. Documentation must at a minimum include the name of the person evaluated, evaluation date/time, media and components used including manufacturer, expiration date and lot number, starting temperature for each interval of incubation, dates of incubation, the results, and the identification of the observer and the person who reads and documents the results.
Interview with Staff Pharmacist #1 on 6/16/21 at 10:45AM, identified he/she was hired on 4/1/21 and did not have 3 consecutive gloved fingertip tests, and that it was only one time upon their initial competency evaluation.
Interview with Pharmacy Technician #2 on 6/16/21 at 10:48AM, identified that he/she was hired in August of 2016 and did not have 3 consecutive gloved fingertip tests, and that it was only one time upon their initial competency evaluation and yearly thereafter.
Review of the Pharmacy Policy and Procedure Manual for the Quality Assurance (QA) / Quality Control (QC) Program plan for Personnel Performance Validation, did not identify a policy for the frequency of and procedure for the gloved fingertip sampling of compounding personnel or indicate what information is required to be included on the report.

c. Observation of PT#1 on 6/16/21 at 2:30PM, identified a doffing PPE procedure in the Ante-Room where PT#1 was observed initially removing the hair covering, then shoe covering, then gown, then gloves and washed hands, dried arms from elbow to fingertips,

sanitized hands with Purell hand sanitizer, crossed the line of demarcation and then came out of the ante room.
Review of the USP 797's instruction for doffing of PPE after leaving the buffer room, identified that the first step in the process is to remove gloves and perform hand hygiene. The gown should be next removed and then the head cover. The shoe covering should be removed one at a time, ensuring that the uncovered foot is placed on the dirty side of the line of demarcation, and performs hand hygiene again. Review of the Waterbury Hospital IV SOP did not identify that removal of gloves as the first step when doffing PPE or that shoe covering should be removed one at a time, ensuring that the uncovered foot is placed on the dirty side of the line of demarcation.

d. Review of facility documentation identified that the last viable air sampling was performed in all compounding areas on February 3, 2021 and reported on February 10, 2021. Further review of facility documentation did not identify surface sample reports.
Review of the current USP 797, identified that surface sampling of all classified areas and pass-through chambers connecting to classified areas for microbial contamination must be conducted at least monthly.
Review of the Pharmacy Policy and Procedure Manual Quality Assurance (QA) / Quality Control (QC) Program plan identified that environmental air sampling is to be conducted bi-monthly for bacteria and fungus. Further review of the policy manual did not identify a monitoring schedule for conducting viable surface samples.
Interview with the Intravenous (IV) Pharmacist on 6/16/21 at 12:40PM, identified that the pharmacy follows the USP Chapter 797 guidelines. It was also identified by the IV Pharmacist that the compounding staff are trained in aseptic technique and that they are occasionally observed for quality assurance, however the observations are not documented. Further interview identified that compounding staff perform gloved fingertip testing upon completing their initial competency and that it is done only one time. It was further identified by the IV Pharmacist, that the last viable air sampling was conducted in February and that there was not another performed after that date. The IV Pharmacist also revealed that he/she has not performed viable surface samples. It was also identified by the IV Pharmacist that h/she is currently in training for the USP 797 and has found a lot of issues with their current policy and procedures that need to be done differently.

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6. Based on observation, interview, and review of facility policy the facility failed to ensure medications were secure in the ICU. The findings include:
   a. The history and physical dated 6/4/21 identified Patient #2 had dementia, seizures, and acute respiratory failure requiring intubation and mechanical ventilation.
   Observation on 6/15/21 at 9:56 AM with RN #1 and Director #1 identified a small clear plastic bag containing medications including: heparin 5,000 units, pantoprazole 40mg, levetiracetam 500mg, olanzapine 5mg, magnesium sulfate 2gm/50ml, insulin glargine 35

units, and chlorhexidine oral rinse, on the bedside table in Patient #2's room.
Interview with RN #1 on 6/15/21 at 9:56 AM identified he/she removed Patient #2's medications from the Omnicell (automated medication dispensing machine) and went to Patient #2's room to administer the medication. RN #1 identified he/she was called out of the room by the unit director and left the medications on the table. RN #1 identified that medications should not be left unattended.
The hospital drug storage policy dated November 2018 directs that all drugs must be stored securely in lockable areas such as the pharmacy department, medication rooms, medication carts, or automated dispensing machines so as to be made inaccessible to unauthorized persons.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (a) Physical plant and/or (b) Administration (2) and/or (c) Medical Staff (2) and/or (e) Nursing Services (1) and/or (i) General (6) and/or (l) infection control (1).

7. Based on observation, interview, and review of facility policy the facility failed to ensure stock medications were not outdated. The findings include:
   a. Tour of the ED with Manager #2 and Director #1 on 6/16/21 at 10:00 AM identified 1 vial of sterile water for injection with a March 2021 expiration date, and 3 out of 4 vials of bacteriostatic water for injection that expired in October 2020 in the trauma room supply cart drawer.
   Interview with Director #1 on 6/16/21 at 10:00 AM identified that a patient care associate rounds daily in the ED to restock and to check for outdated supplies including sterile and bacteriostatic water. Director #1 identified sterile water for injection and bacteriostatic water for injection come from central supply and not the pharmacy therefor a patient care associate may check for outdates and restock as needed.
   The hospital drug storage policy dated November 2018 identified all bulk floor stock medications should be stored as per the manufacturer's recommendations.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (2) (d) Medical records (3) and/or (e) Nursing Services (1) Maternity service.

8. Based on clinical record reviews, review of facility documentation, review of policies, and interviews for one of three sampled patients (Patient #20) who was reviewed for pain assessment, the hospital failed to ensure the Neonatal Infant Pain Scale (NIPS) was completed following a painful procedure consistent with the facility's policy. The findings include:
   a. Patient # 20 was a male infant delivered on 6/11/21 at 2:58AM to Patient #31.
   A physician's order dated 6/11/21 at 2:50AM directed, Circumcision once for Patient #20.
   Another physician's order dated 6/12/21 at 7:18PM directed post circumcision assessment secondary to completed circumcision procedure.
   Review of Patient #20's pain assessment flowsheets- Neonatal Infant Pain scale (NIPS) on 6/15/21 at 10:45AM with Manager #2 and RN #5 identified Patient #20's NIPS score was

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assessed and documented on 6/12/2021 at 8:47AM (time of circumcision procedure). Further review of Patient #20's clinical record identified that following the Circumcision procedure NIPS score for Patient #20 was next completed and documented on 6/12/21 at 7:15PM (10 hours and 28 minutes after completion of last NIPS assessment). Patient #20's clinical record failed to reflect documentation Patient #20's pain was assessed one - hour post circumcision consistent with the facility's policy.
In an interview Manager #2 on 6/15/21 at 10:46AM, Manager #2 indicated it was the expectation that staff completed pain assessments after a circumcision procedure according to the facility's policy and practice.
Subsequent to the investigation, Manager #2 stated that corrective plan would include education of the staff to include review of the Circumcision policy.
Review of the Circumcision of the male Newborn Pain Management policy directed, one-hour post procedure, the nurse will assess for excess bleeding at the circumcision site and document the NIPS score in the newborn chart. NIPS scores are assessed and documented with the administration of acetaminophen and with routine vital signs each shift for 24 hours after the circumcision.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (3) (e) Nursing Services (1) and/or (i) General (6).

9. Based on observations, review of hospital's documentation, review of facility's policy, and interviews, the facility failed to ensure temperatures of a fluid warmer cabinet was monitored and documented consistent with the facility's policy to ensure safe patient care. The findings include:
   a. During a tour of operating room #2 (Labor and delivery) with RN #2 (clinical Operation Manager) on 6/15/21 at 12:15PM observation of the fluid warmer and review of the fluid warmer temperature log dated 6/1/21 to 6/15/21 failed to identified documentation the temperature for the fluid warmer cabinet was monitored and documented for five of the fifteen days reviewed.
   In an interview with Manager #2 on 6/15/21 at 12:30PM, Manager #2 indicated it was the expectation that temperatures of the fluid warmer cabinet were checked and documented daily. Manager #2 identified it was the responsibility of the Surgical technician to monitor the temperatures and complete documentation on the temperature log. Manager #2 indicated that when the surgical technician was not available it was the responsibility of the charge nurse to monitor the temperature and complete the log.
   Subsequent to the observation, Manager #2 indicated that an audit of the temperature monitoring of the fluid warmer cabinet would be initiated.
   Review of the Fluid/Blanket warming policy directed the temperature of the warming cabinets will be checked daily and entered into the log sheet. Any corrective actions will be noted and recheck will be performed one hour after corrective action.

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The following are violations of the Regulation of Connecticut State Agencies Section 19-13-D3 (h) Dietary Services and/or (i) General (6) and/or (k) Maternity service and/or (l) infection control (1).

10. Based on observations, review of facility documentation, review of policies, and interviews, the facility failed to ensure temperatures of the refrigerator used to store snacks for patients were monitored to ensure food safety, and failed to ensure a pantry refrigerator was maintained in a clean and sanitary condition. The findings include:
    a. During a tour of the Labor and Delivery, Recovery and Postpartum (LDRP)Unit with Manager #2 and RN #6 on 6/15/21 at 9:55AM observation of a pantry refrigerator which contained fifteen cartons of milk and bowl of individual sized coffee creamers failed to identify a thermometer located in the refrigerator.
    An interview with Manager #5 (Clinical Nutrition Manager) on 6/15/21 at 2:15PM indicated she was unable to explain the reason a thermometer was not located in the refrigerator. Also, Manager #5 stated she was unable to locate temperature logs with documented daily temperatures for the refrigerator. Manager #5 indicated it was the responsibility of the dietary Aide to stock the refrigerator and complete the temperature logs daily.
    Subsequent to the surveyor's observation, a thermometer was placed in the refrigerator and Manager #5 stated that the issue of the missing thermometer would be investigated.
    Review of the Patient Food Service policy directed Food and nutrition Services personnel are responsible for daily temperature monitoring of unit refrigerators on floor stock sheets.
    b. A tour of the P 5 Unit of the Hospital and observation of the pantry with Manager #4 on 6/16/21 at 9:15AM identified the freezer that contained orange ice and ice cream had brown stains and debris. The refrigerator containing juices, sodas and coffee creamers was noted to have a dry yellow stain approximately 8 inches wide down the entire back wall of the refrigerator. Also, four removable drawers located on the second self of the refrigerator as well as two drawers located in the lower section of the refrigerator had built- up, caked on brown residue and debris.
    An interview with Manager #4 on 6/16/21 at 9:17PM identified that the dietary department was responsible for cleaning the pantry refrigerator.
    In an interview with the Director of Food and Nutrition on 6/16/21 at 10:30PM identified that the Dietary Aide was responsible for checking refrigerator temperatures, rotate stock and clean the refrigerators daily. The Director indicated it was the expectation that pantry refrigerators were cleaned daily and stated the stains identified indicated the refrigerator and freezer were not cleaned consistent with the practice of the facility.
    Review of the Patient Food Service policy directed catering associate is responsible to cleaning the refrigerators daily with a FDA approved germicide/disinfectant or general solutions (as appropriate) dispensed from approved dispensing system.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (e) Nursing Services (1) and/or (g) Pharmacy and/or (i) General (6) and/or (l) infection control (1).

11. Based on observations, review of facility policies, and interviews, the Hospital failed to date an

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open multi use medication bottle and failed to discard expired saline solutions according to the facility's policy. The findings include:

a. A tour of the Labor and delivery Recovery and Delivery (LDRP) unit and observation of the medication room with Manager #2, RN #5, and RN #6 on 6/15/21 at 10:15AM identified 1 opened undated bottle of Glycerin with approximately half of the contents. Also, observation was made of ten – 10 mil bottles of 0.9% normal saline with expiration date of 5/21.

An interview with Manager #6 on 6/15/21 at 10:20AM identified that the Patient Care associates were responsible for checking and removing outdated solutions from the medication storage area. Manager #6 was unable to explain the reason expired medications were not discarded and was unable to identify when the container of glycerin was opened.

In an interview with the interim Director of Pharmacy on 6/17/21 at 12:05PM identified that stock bottles of glycerin were treated as multi vial and were good for 28 days after opened. Subsequent to the surveyor's observation, Manager #9 discarded the expired normal saline solutions and the bottle of glycerin.

Review of the Hospital's Drug Storage policy directed all bulk floor stock medications should be stored as per the manufacture's recommendations, any alterations in the manufacturer's container may result in a change in potency, and should be dated according to the packaging policy in the pharmacy manual. The Policy further directed that multi dose vials are good for 28 days after initial access.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 Short Term Hospitals, General and Special (a) Physical Plant (2) & (i) General (6).

12. During a tour of Waterbury Hospital on June 15, 2021 and subsequent documentation review, the following was observed:
    a. On 06/15/21 at various times throughout the day the surveyor, accompanied by the Director of Biomedical Engineering & Facility Operations, observed that the facility failed to ensure that all means of egress are maintained free of all obstructions and impediments to full and instant use in case of fire or any other emergency as required by section 14.4.1 of the Connecticut Fire Prevention Code. i.e; All exit access corridors in the basement area are being utilized for the storage of equipment, beds, furniture, tools, and cleaning supplies.

Approved
7/29/21
SHN

Waterbury Hospital

Waterbury HEALTH

July 2, 2021

Susan H. Newton, RN, BS
Supervising Nurse Consultant
Facility Licensing and Investigations Section
State of CT, Department of Public Health
410 Capital Avenue
Hartford, CT 06134-0308

Dear Ms. Newton,

We are in receipt of your letter dated June 21, 2021 identifying the violations noted during your unannounced visits made to Waterbury Hospital between June 15, 2020 and June 17, 2021.

Attached is the plan of correction for the deficiencies identified during the survey. Waterbury Hospital makes its best efforts to operate in full compliance with both state and federal laws and regulations. Nothing included in these plans of correction is an admission otherwise. Waterbury Hospital submits this plan of correction to comply with its regulatory obligations.

Please contact me with any questions or concerns.

Respectfully,

Gina Spatafore, MSN, RN
Director, Performance Improvement
203-573-7633
gina.spatafore@wtbyhosp.org

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (e) Nursing Services (l) and/or (i) General (6).

1. Based on clinical record review and interview for one of three patients receiving hemodialysis (Patient #30) the facility failed to ensure that the patient's prescription was complete to includea prescribed blood rate. The finding included:
   a. Patient# 30's diagnoses included renal failure. Review of the patient's hemodialysis orders dated 6/16/2021 directed a one-time unscheduled hemodialysis treatment for ultrafiltration using a Revaclear dialyzer and an ultrafiltration goal of 4.5 liters however the order failed to include a prescribed Blood Flow Rate (BFR).
   Observation on 6/16/21 at 1:20 PM identified that the patient's treatment was initiated witha Revaclear 300 dialyzer, through the patient's Central Venous Catheter and the BFR set at 300 ml/min.
   Subsequent to surveyor inquiry, RN #8 acknowledged that physician's order should have specified the blood flow rate and although she did not contact the prescribing physician, it was a sequential treatment for ultrafiltration, it was common to run the BFR at 300 ml/min. In a subsequent interview on 6/17/21 at 11:30 AM, RN# 9 stated that all hemodialysis orders should include the blood flow rate and in the case that the blood flow rate is not included in the order, the nurse would contact the prescribing physician to obtain the rate with a telephone order, prior to starting the treatment.
   Interview with the clinical nurse specialist on 6/16/21 at 1:40 PM identified that the blood flow rate should have been included in the hemodialysis order and acknowledged that this practice would need to be addressed to tighten up the process. Review of the hemodialysis policy and procedures identified that hemodialysis is administered in accordance with the prescribed treatment that directs the type of dialyzer, the length of treatment, the access, the dialysate components and the dialysate (DFR) and blood flow rates (BFR).

Measures to prevent recurrence:
Effective June 24, 2021 the DaVita Group Hospital Services Administrator re-educated the DaVita RN staff who provide dialysis contracted services at Waterbury Hospital on the requirement to obtain an order for blood flow rates. Effective June 24, 2021 the Director of Dialysis Services sent a global email to the Nephrologists that have oversight for patient's receiving dialysis services advising them to enter the blood flow rate into the comments for dialysis orders in the UF order set. Effective 7/1/2021 the NEPH Acute Hemodialysis Order set will be revised in the Hemodialysis (Ultrafiltration Only) section to include a drop-down for Blood Flow Rate.
To ensure on-going compliance the DaVita Group Hospital Administrator or designee will audit 15 random dialysis records per month or 100% if less than 15 cases performed in month to ensure compliance with obtaining a provider order for blood flow rate. Audit results will be

reported monthly at the Performance Improvement Safety Committee until three consecutive months of 100% compliance is achieved.

Effective date of correction action plan: 7/1/2021

Responsible person by title: CNO

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (a) Physical plant and/or (b) Administration (2) and/or (c) Medical Staff (2) and/or (e) Nursing Services (l)and/or (i) General (6) and/or (I) infection control (1).

2. Based on a tour of the operating room (OR), review of facility policies, observations and interviews the hospital failed to ensure proper hair coverage in restricted areas, failed to ensuresurgical policies were complete and failed to ensure surgical/procedural equipment was maintained or properly stored. The finding includes:
    a. A tour of the main OR was conducted on 6/15/21 with Director #2. Observations on 6/15/21at 10:00 AM identified Resident (R) #1 in OR #4 during a procedure. Although R #1 had donned a surgical mask. His full beard was not contained within the surgical mask. The observation further noted the anesthesia provider had donned a skull type surgical cap and approximately three inches of hair was exposed at the back of the head. An observation On 6/15/21 at 10:21 AM identified white beard covers and full blue head/side of face caps were available in the semi- restricted area of the OR.

    Observation on 6/15/21 at 10:30 AM noted MD #1 in the semi restricted area of the ReedOR area had donned a skull type surgical cap and approximately two and one half to threeinches of hair was exposed at the back of the head/neck. MDF #1 subsequently donned a bouffant cap over the skull cap per the request of Director #1.

    Interview with Director #2 on 6/15/21 at 10:01 AM noted that the hospital followed the standards of the Association of peri-Operative Registered Nurses (AORN) in the surgicalareas. Director #2 noted that she believed the surgical attire policy called for all hair to becovered when in the semi- restricted and restricted surgical areas and did not know if thehospital had beard covers.

    The hospital policy entitled surgical attire identified that skull caps may be worn if close to the totality of the hair is covered and only a limited amount of hair on the nape of the neckor sideburn remain uncovered. The policy further identified that disposable skull caps thatdo not cover close to the totality of the hair should not be worn, or if worn, covered with adisposable bouffant hair cap. The hospital policy did not direct staff for beard coverage, or the use of beard covers.

    AORN copyright 2012- 2021 recommended to cover a beard when entering the restrictedareas and while preparing items in the clean assembly of the sterile reprocessing area.

    A tour of the Reed OR area was conducted with Director #2 on 6/15/21. Observation of OR#5 identified peeling, chipped paint on the base of the robotic monitor stand and a total of eight our rusted castors on the base of two intravenous poles.

Interview with Director #2 on 6/15/21 at 10:34 AM indicated that OR equipment was sanitized with the 3- minute contact germicidal. The peeling paint and rust rendered theequipment unable to be properly sanitized.
The hospital policy entitled Cleaning and Disinfection of Operating Room identified thatORs will be cleaned after every surgical procedure. The hospital policy entitled Cleaningand Disinfection of Non- Critical Equipment/Items in Healthcare directed to use an approved disinfectant to routinely cleanse non- critical items to include IV pumps.
A tour of the Reed pre/postoperative area was conducted with Director #2 on 6/15/21. Observations on 6/15/21 at 10:34 AM noted two older stretchers with multiple areas of ripped and peeling vinyl exposing the foam filling.
Interview with Director #2 on 6/15/21 at 10:34 AM indicated that OR equipment wassanitized with the 3- minute contact germicidal.
The hospital policy entitled Cleaning and Disinfection of Non- Critical Equipment/Items in Healthcare directed to use an approved disinfectant to routinely cleanse non- critical items toinclude stretchers.
A tour of the Gastroenterology department was conducted with Director #3 on 6/15/21. Observation of the scope storage closets on 6/15/21 at 11:40 AM identified two of the three closets with ten reprocessed scopes. The two storage closets lacked vents to ensure airflow.Interview with Director #3 on 6/15/21 at 11:40 AM noted that the closets had been in use since the department moved to the new location.
The hospital policy entitled Gastroenterology Infection Prevention identified the scopes are hung in storage cabinets with adequate ventilation.

Measures to prevent recurrence:
Under the direction of the Executive Director of Surgery, effective 6/21/2021, all staff in restricted areas will be required to wear a bouffant cap and beard coverings if applicable. Beginning 6/21/2021 the OR educator began education during daily huddles regarding proper hair coverage requirements. Additionally, signage was posted throughout the OR reminding staff of proper hair coverage requirements.
The *OR Dress Code* policy was revised to include proper beard coverage requirements. The updated policy was sent via email to OR staff with a read receipt acknowledgement to be returned by 7/2/2021.
To ensure on-going compliance 15 direct observations will be performed to ensure proper hair coverage. Any noncompliance will be immediately corrected and on the spot education provided. Audit results will be reported monthly at the Performance Improvement Committee until three consecutive months of 100% compliance is achieved.
On 6/15/2021 the IV poles with rusted castors and the vinyl stretchers were removed from service. A thorough inspection of all OR IV poles was conducted and any IV poles with rusted castors were removed from service for repair. On 6/24/2021 the robotic monitor was removed and repaired.
To ensure on-going compliance a weekly audit of equipment, including IV poles, mattresses and monitors will be conducted. Any equipment in disrepair will be removed from service. Audit results will be compiled monthly and reported to the Performance Improvement Committee until three consecutive months of 100% compliance is achieved.

Effective date of correction action plan: 7/2/2021

Responsible person by title: Executive Director Surgery

Measures to prevent recurrence:
Effective 7/2/2021 the storage closet doors were remodeled to include ventilation for proper airflow in compliance with the policy *Gastroenterology Infection Prevention.*

Effective date of correction action plan: 7/2/2021

Responsible person by title: Clinical Manager Gastroenterology

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 ((b)Administration (2) and/or (c) Medical Staff (2) and/or (d) Medical records (3) and/or (i) General (6).

3. Based on a tour of the Gastroenterology department, review of three operative/procedural medical records and interviews for one of three surgical patients (P #4), the hospital failed toensure that the physician documented an immediate operative report. The finding includes:

    a. A tour of the gastroenterology department was conducted with Director #3 on 6/15/21. Observation on 6/15/21 at 11:18 AM noted that the department had three stretchers in thepre/postoperative care unit and all three stretchers were empty and clean. A review of electronic medical records (EMR) was conducted with RN #2 on 6/15/21 at 11:50 AM.

    P #4 was admitted for a colonoscopy by MD #2 on 6/15/21. The EMR identified that P #4'scolonoscopy was performed by MD #2 and P #4 was discharged at 10:56 AM. The medical record lacked an immediate operative or operative report following the procedure and prior to the patient's discharge.

    P #5 was admitted for a colonoscopy by MD #2 on 6/15/21. The EMR identified that P #S's colonoscopy was performed by MD #2 and an immediate operative report for P #5 wasobserved in P #S's EMR.

    Interview with RN #2 on 6/15/21 at 11:50 AM noted that MD #2 usually dictated the immediate operative report in the procedure room and immediately after the patient'sprocedure.

    The hospital Rules and Regulations of the Medical Staff identified that for all outpatients and in patients immediately following an invasive procedure or operation a brief operative/procedure report must be placed in the patient's hospital record and signed by themedical staff who performed the procedure.

    Public Act No. 15-11 Section 1. (1) (4) (c), An Act Concerning Persons Who Decontaminate Reusable Medical Equipment or Devices.

    Based on a tour of the Central Sterile and Gastroenterology Departments, review of personnel files and interviews for one of three reprocessing techs (Tech#1), the hospitalfailed to ensure that required yearly education was maintained. The finding includes:

A tour of the Gastroenterology department was conducted on 6/15/21. The tour identified that Tech #1 was the lead technician in the department and reprocessed scopes using high level disinfection.
Review of Tech #1's personnel record on 6/17/21 at 12:50 AM identified that Tech #1 completed 10 continuing education units (CEUs) for the 2019 year. The review furtheridentified that CEUs for the year 2020 were not located in the personnel file.
Interview with the Performance Specialist on 6/17/21 at 1:00 PM noted that the new educator informed Tech #1 that she was not required to maintain annual CEUs in her current role.
According to Public Act No. 15-11 Section 1. (4) (c), "Central service technician" means a person who decontaminates, inspects, assembles, packages and sterilizes reusable medical instruments or devices in a health care facility. A central service technician shall complete a minimum of ten hours of continuing education annually. The continuing education shall be in areas related to the functions of the ventral service technician.

Measures to prevent recurrence:
Immediately on 6/15/2021 the Clinical Manager of Gastroenterology provided coaching to the MD who performed the procedure regarding the hospital Rules and Regulations requirement that for all out patients and in patients immediately following an invasive procedure or operation a brief operative/procedure report must be placed in the patient's hospital record and signed by the medical staff who performed the procedure. On 6/29/2021 the Clinical Manager of Gastroenterology sent a global email to the Gastroenterology providers to re-enforce the hospital Rules and Regulations of the Medical Staff that for all out patients and in patients immediately following an invasive procedure or operation a brief operative/procedure report must be placed in the patient's hospital record and signed by the medical staff who performed the procedure.
To ensure on-going compliance the Clinical Manager of Gastroenterology or designee will perform an audit of 10 records per month to ensure immediate documentation of procedure.

Effective date of correction action plan: 6/29/2021

Responsible person by title: Clinical Manager Gastroenterology

Measures to prevent recurrence:
Effective 6/15/2021 the Clinical Manager of Gastroenterology informed the GI techs they must obtain 10 CEUs prior the December 31, 2021. Beginning 6/21/2021 the OR Educator began investigating opportunities for CEUs with a gastroenterology component for the Gastroenterology Technologists to obtain CEUs.
To ensure on-going compliance the Clinical Manager of Gastroenterology will add verification of 10 CEUs as part of the yearly performance review.

Effective date of correction action plan: 6/15/2021

Responsible person by title: Clinical Manager Gastroenterology

The following is a violation of the Regulation of Connecticut State Agencies, Section 19-13-03 (b),Administration (2) (h) Dietary Services and/or (i) General (6) and/or (I) infection control (1).

4. Based on observation during a tour of the facility, review of facility policy and interview withfacility staff, the facility failed to ensure that refrigerated food items were removed upon expiration. The Findings include:
   a. Observation during a tour of the facility's kitchen area, on 6/15/21 at 9:30AM, identifiedthat refrigerator #3, in the main kitchen, contained 2 containers of chicken soup that were prepared on 6/10/21, however, only one of the labels specified the expiration date as 6/13/21. The other container did not have the expiration date written on the label.
   Review of facility policy for Food and Supply Storage identified that all food items in foodpreparation shall be stored in such a manner as to prevent contamination to maintain safety and wholesomeness of the food for human consumption. Unused portions of foods preparedon site, should be covered, labeled and dated. Further review of the policy identified that all sections of the Morrison orange label should be completed and that both reheated and not reheated, unused portions of foods are good for 3 days and that food past the use-by date or expiration date should be discarded.
   Interview with the Registered Dietician (RD) on 6/15/21 at 9:45AM, identified that the dietary managers should be monitoring the refrigerators daily in the morning and should immediately remove expired items. It was also identified by the Registered Dietician that prepared items in the refrigerator, should have the date of preparation and expiration dateswritten on the label.

Measures to prevent recurrence:
Effective June 22, 2021 during daily safety huddle the Director of Food and Nutrition re-enforced education on the *Food and Supply Storage* policy which details refrigerated storage life of foods, freezer storage life of foods, dry storage life of foods and proper refrigerator and freezer storage. Additionally, retraining of proper labeling and orange label for dating was done during safety huddle. Staff were required to acknowledge understanding by signing-off on the re-training. On June 22, 2021, the following charts were posted in the kitchen area as a visual cue of food and supply storage requirements:

- Refrigerated Storage of Life of Foods
- Freezer Storage of Life of Foods
- Dry Storage of Life of Foods
- Proper Refrigerator and Freezer Storage

To ensure ongoing compliance on June 22, 2021 "check all refrigerators for outdated items" was added to the opening and closing managers check list. The Director of Food and Nutrition or designee will perform a weekly audit of the manager's checklist to ensure the check list item is completed. The data from the audit will be reported monthly to the Performance Improvement Safety committee until three consecutive months of 100% compliance is achieved.

Effective date of correction action plan: 7/1/2021

Responsible person by title: Director of Food and Nutrition

The following are violations of the Regulation of Connecticut State Agencies Section 19-13-D3 (b)Administration (2) and/or (g) Pharmacy and/or (i) General (6) and/or (I) infection control (1).

5. Based on observation during a tour of the facility, review of facility policy and interviews with facility staff, the facility failed to ensure that compounding pharmacy staff are following asepticteclmique prior to compounding procedures and/or that the policy follows USP Chapter 797 standards for Compounding Sterile Products. The findings include:
   a. Observation of Pharmacy Technician #1 (PT#1) on 6/16/21 at 2:20PM, identified a donningPPE procedure in the Ante room. Although hand hygiene was performed correctly, PT# 1 was observed drying their hands and arms starting from the fingertips up to the elbows, andthen was observed immediately bringing the drying cloth back down to the fingertips. Review of PT#l 's personnel file identified that h/she was trained on the Pharmacy Policy and Procedures for the Intravenous (IV) Room, however the date of the training was not indicated. Review of the Pharmacy Policy and Procedure Manual, Appendix B: Waterbury Hospital Intravenous (IV) Room Standard Operating Procedures (SOP) for the Non-Hazardous DrugBuffer Room and review of the United States Pharmacopeia Chapter 797 for Compounding Sterile Preparations (USP 797), identified that after hand hygiene is complete, hands and arms are rinsed from fingertips to elbows, and then pat dry going from fingers to elbow. The IV SOP and the USP 797 standard do. not identify that the drying towel should be. brought back down to the fingers after drying the elbow, Further review of the IV SOP identified that competency in aseptic techniques of all compounding pharmacists and technicians is observed, evaluated and recorded during orientation and training and at least every 6 months or whenever unacceptable techniques are observed or detected. Review of the USP 797, identified that all compounding personnel must be visually observed initially and every 6 months while performing hand hygiene and garbing procedures and that the visual audit must be documented, and the documentation maintained to provide a record of personnel competency.
   b. Review of the compounding pharmacy staffs gloved fingertip test results, identified that 4 of 4 sampled staff members, did not have 3 consecutive initial gloved fingertip tests performed. Further review of the gloved finger test results identified that the documentationdid not include the media and components used manufacturer information, the starting temperature for each interval of incubation, and the identification of the observer and the person who reads and documents the results.
   Review of the USP 797, identified that before being allowed to independently compound, all compounders must successfully complete an initial competency evaluation, including visual observation and gloved fingertip and thumb sampling on both hands, no fewer than 3separate times. After the initial competency

evaluation, compounding personnel must successfully complete gloved fingertip and thumb sampling at least every 6 months after completing the media-fill test. Results of the evaluation and corrective actions, in the event of failure, must be documented and the documentation maintained to provide a record and long-term assessment of personnel competency. Documentation must at a minimum include the name of the person evaluated, evaluation date/time, media and components used including manufacturer, expiration date and lot number, starting temperature for each interval of incubation, dates of incubation, the results, and the identification of the observer and the person who reads and documents the results.
Interview with Staff Pharmacist #1 on 6/16/21 at 10:45AM, identified he/she was hired on 4/1/21 and did not have 3 consecutive gloved fingertip tests, and that it was only one time upon their initial competency evaluation.
Interview with Pharmacy Technician #2 on 6/16/21 at 10:48AM, identified that he/she was hired in August of 2016 and did not have 3 consecutive gloved fingertip tests, and that itwas only one time upon their initial competency evaluation and yearly thereafter.
Review of the Pharmacy Policy and Procedure Manual for the Quality Assurance (QA)/ Quality Control (QC) Program plan for Personnel Performance Validation, did not identify a policy for the frequency of and procedure for the gloved fingertip sampling of compoundingpersonnel or indicate what information is required to be included on the report.

c. Observation of PT#l on 6/16/21 at 2:30PM, identified a doffing PPE procedure in the Ante-Room where PT#l was observed initially removing the hair covering, then shoe covering, then gown, then gloves and washed hands, dried arms from elbow to fingertips, sanitized hands with Purell hand sanitizer, crossed the line of demarcation and then cameout of the ante room.
Review of the USP 797's instruction for doffing of PPE after leaving the buffer room, identified that the first step in the process is to remove gloves and perform hand hygiene. The gown should be next removed and then the head cover. The shoe covering should be removed one at a time, ensuring that the uncovered foot is placed on the dirty side of the lineof demarcation, and performs hand hygiene again. Review of the Waterbury Hospital IV SOP did not identify that removal of gloves as the first step when doffing PPE or that shoe covering should be removed one at a time, ensuring that the uncovered foot is placed on the dirty side of the line of demarcation.

d. Review of facility documentation identified that the last viable air sampling was performedin all compounding areas on February 3, 2021 and reported on February 10, 2021. Further review of facility documentation did not identify surface sample reports.
Review of the current USP 797, identified that surface sampling of all classified areas and pass-through chambers connecting to classified areas for microbial contamination must be conducted at least monthly.
Review of the Pharmacy Policy and Procedure Manual Quality Assurance (QA)/ Quality Control (QC) Program plan identified that environmental air

sampling is to be conducted bi-monthly for bacteria and fungus. Further review of the policy manual did not identify a monitoring schedule for conducting viable surface samples.
Interview with the Intravenous (IV) Pharmacist on 6/16/21 at 12:40PM, identified that the pharmacy follows the USP Chapter 797 guidelines. It was also identified by the IV Pharmacist that the compounding staff are trained in aseptic technique and that they are occasionally observed for quality assurance, however the observations are not documented. Further interview identified that compounding staff perform gloved fingertip testing upon completing their initial competency and that it is done only one time. It was further identified by the IV Pharmacist, that the last viable air sampling was conducted in February and that there was not another performed after that date. The IV Pharmacist also revealed that he/she has not performed viable surface samples. It was also identified by the IV Pharmacist that h/she is currently in training for the USP 797 and has found a lot of issues with their current policy and procedures that need to be done differently.

Measures to prevent recurrence:
On June 16, 2021, the IV pharmacist provided one to one coaching to the pharmacy technician on proper donning procedure per the Waterbury Hospital policy. The policy has been updated with proper donning and doffing procedures. All active Waterbury pharmacy staff have been asked to acknowledge by 7/2/2021. To ensure ongoing compliance a random visual audit of donning and doffing procedure will be done. Any noncompliance will result in on the spot education. Audits will be done three times monthly until three consecutive months of 100% compliance is achieved. Audit results will be reported monthly to the Performance Improvement Safety Committee.

Effective date of correction action plan: June 16, 2021

Responsible person by title: Director Pharmacy

Measures to prevent recurrence:
On June 16, 2021, on the day of the survey, the Director of Pharmacy modified the *Gloved Fingertip Test and Media Fill Test Report* to include documentation of media and components used manufacturer information, the starting temperature for each interval of incubation, and the identification of the observer and the person who reads and documents the results.
On June 22, 2021, one of the four pharmacy staff identified in the deficiency report completed the three consecutive gloved fingertip testing. Three of the four pharmacy staff, who are per diem, have been scheduled for gloved fingertip testing to be completed by 7/30/2021. Pharmacy staff who have not completed the gloved fingertip testing will not be allowed to compound until testing is complete. The next step of testing will be 2022 for this set of staff. No new staff will be allowed to compound until completion of media fill and glove finger (x3).
To ensure on-going compliance with media fill and gloved fingertip testing, the Director of Pharmacy or designee will perform a quarterly audit of staff compliance with gloved fingertip and media fill testing. The results will be reported on a quarterly basis to the Infection Prevention

Committee and Performance Improvement Committee.
Effective 7/16/2021 the *Sterile Compounding* policy has been updated to reflect the frequency of and procedure for gloved fingertip testing of compounding personnel. The policy was also updated to indicate the information required to be included on the report.
On 6/18/2021, pharmacy staff were educated to the change in the policy via department huddle and email with read receipt. Additionally, annual attestation of the policy is done via HealthStream.

Effective date of correction action plan: 7/30/2021

Responsible person by title: Director, Pharmacy Services

Measures to prevent recurrence:
Effective June 18, 2021, the Standard Operating Procedure (SOP) portion of the *Sterile Compounding* policy was revised to reflect the sequential steps for doffing PPE after leaving the buffer room as removal of gloves and perform hand hygiene as the first step, followed by removal of gown, then head cover, followed by removal of shoe covering one at a time ensuring that the uncovered foot is placed on the dirty side of the line of demarcation, and perform hand hygiene again.
Effective 6/18/2021 pharmacy staff were educated to the change in the SOP during staff huddle. Additionally, education was sent via email with read receipt acknowledgement by July 2, 2021.

Effective date of correction action plan: July 2, 2021

Responsible person by title: Director of Pharmacy Services

Measures to prevent recurrence:
On June 18, 2021, the *Sterile Compounding* policy was updated to reflect the current USP 797 requirements and standards of practice to perform surface sampling every six months. Surface sampling was completed on February 3, 2021 with a sampling scheduled six months following in August 2021. The USP 797 standards referenced in the deficiency are in the draft guidelines which have not been approved (reference usp.org). Current USP 797 standards indicate surface sampling in all ISO classified areas is to be done on a periodic basis with no indication of specific time.

Effective date of correction action plan: (date)

Responsible person by title: Director, Pharmacy Services

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b)Administration {2) and/or {e) Nursing Services (1) and/or (i) General (6).

6. Based on observation, interview, and review of facility policy the facility failed to ensuremedications were secure in the ICU. The findings include:
    a. The history and physical dated 6/4/21 identified Patient #2 had dementia, seizures, and acuterespiratory failure requiring intubation and mechanical

ventilation.
Observation on 6/15/21 at 9:56 AM with RN #1 and Director #1 identified a small clearplastic bag containing medications including: heparin 5,000 units, pantoprazole 40mg, levetiracetam 500mg, olanzapine 5mg, magnesium sulfate 2gm/50ml, insulin glargine 35 units, and chlorhexidine oral rinse, on the bedside table in Patient #2's room.
Interview with RN #1 on 6/15/21 at 9:56 AM identified he/she removed Patient #2's medications from the Omnicell (automated medication dispensing machine) and went to Patient #2's room to administer the medication. RN #1 identified he/she was called out of the room by the unit director and left the medications on the table. RN #1 identified that medications should not be left unattended.
The hospital drug storage policy dated November 2018 directs that all drugs must be storedsecurely in lockable areas such as the pharmacy department, medication rooms, medicationcarts, or automated dispensing machines so as to be made inaccessible to unauthorized persons.

Measures to prevent recurrence:
On 6/15/2021 the Executive Director of Critical Care immediately providing coaching to the RN involved in the noted deficiency regarding safe medication handling practices. Effective 6/30/2021 an algorithm for safe medication handling will be created and reviewed with all ICU RNs on their next shift with signed acknowledgement.
To ensure ongoing compliance weekly random observations will be performed to validate compliance with safe medication handling practices. Any deviation from compliance will be addressed immediately with on the spot coaching. Results of the weekly observations will be reported monthly to the Performance Improvement Safety Committee until three consecutive months of 100% compliance is achieved.

Effective date of correction action plan: 7/16/2021

Responsible person by title: Executive Director Critical Care

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (a) Physical plant and/or (b) Administration (2) and/or (c) Medical Staff(2) and/or (e) Nursing Services (1)and/or (i) General (6) and/or (I) infection control(1).

7. Based on observation, interview, and review of facility policy the facility failed to ensure stockmedications were not outdated. The findings include:
   a. Tour of the ED with Manager #2 and Director #1 on 6/16/21 at 10:00 AM identified 1 vial of sterile water for injection with a March 2021 expiration date, and 3 out of 4 vials of bacteriostatic water for injection that expired in October 2020 in the trauma room supply cart drawer.
   Interview with Director #1 on 6/16/21 at 10:00 AM identified that a patient care associate rounds daily in the ED to restock and to check for outdated supplies including sterile and bacteriostatic water. Director#1 identified sterile water for injection and bacteriostatic water for injection come from central

supply and not the pharmacy therefor a patient care associatemay check for outdates and restock as needed.
The hospital drug storage policy dated November 2018 identified all bulk floor stockmedications should be stored as per the manufacturer's recommendations.

Measures to prevent recurrence:
Effective 7/12/2021 use of a checklist for the trauma room supply cart will be instituted to include checking for expiration dates on medications and supplies to be completed daily by the assigned PCA.
To ensure ongoing compliance, the manager of the ED or designee will perform a weekly audit of the checklist to validate compliance. The data from the audit will be reported monthly to the Performance Improvement Safety committee until three consecutive months of 100% compliance is achieved.

Effective date of correction action plan: 7/12/2021

Responsible person by title: Executive Director ED

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (2) (d)Medical records (3) and/or (e) Nursing Services (I) Maternity service.

8. Based on clinical record reviews, review of facility documentation, review of policies, and interviews for one of three sampled patients (Patient #20) who was reviewed for pain assessment, the hospital failed to ensure the Neonatal Infant Pain Scale (NIPS) was completedfollowing a painful procedure consistent with the facility's policy. The findings include:
    a. Patient# 20 was a male infant delivered on 6/11/21 at 2:58AM to Patient #31. A physician's order dated 6/11/21 at 2:50AM directed, Circumcision once for Patient #20. Another physician's order dated 6/12/21 at 7:18PM directed post circumcision assessment secondary to completed circumcision procedure. Review of Patient #20's pain assessment flowsheets- Neonatal Infant Pain scale (NIPS) on 6/15/21 at 10:45AM with Manager #2 and RN #5 identified Patient #20's NIPS score was assessed and documented on 6/12/2021 at 8:47AM (time of circumcision procedure). Further review of Patient #20's clinical record identified that following the Circumcision procedure MIPS score for Patient #20 was next completed and documented on 6/12/21 at 7:15PM (10 hours and 28 minutes after completion of last NIPS assessment). Patient #20's clinical record failed to reflect documentation Patient #20's pain was assessed one - hour post circumcision consistent with the facility's policy.
    In an interview Manager #2 on 6/15/21 at I0:46AM, Manager #2 indicated it was the expectation that staff completed pain assessments after a circumcision procedure according to the facility's policy and practice.
    Subsequent to the investigation, Manager #2 stated that corrective plan would includeeducation of the staff to include review of the Circumcision policy.

Review of the Circumcision of the male Newborn Pain Management policy directed, one- hour post procedure, the nurse will assess for excess bleeding at the circumcision site and document the NIPS score in the newborn chart. NIPS scores are assessed and documented with the administration of acetaminophen and with routine vital signs each shift for 24 hoursafter the circumcision.

Measures to prevent recurrence:
Beginning 6/16/2021 the Clinical Operations Manager for the Family Birthing Center reinforced proper documentation of the NIPS score during daily huddles. Information from daily huddles is shared on all shifts. In addition, beginning 6/25/2021, staff are required to read the *Circumcision Pain Management* policy and attest to their understanding of the documentation requirements outlined in the policy.
To ensure on-going compliance, the Director of Family Birthing Services, or designee will perform an audit on ten random circumcision charts per month to ensure compliance with one-hour NIPS documentation. Any noncompliance will result in coaching. Results of the audit will be presented at the Performance Improvement Safety Committee until three consecutive months of 100% compliance is achieved.

Effective date of correction action plan: 7/12/2021

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (3) (e)J\Jursing Services (I) and/or (i) General (6).

9. Based on observations, review of hospital's documentation, review of facility's policy, and interviews, the facility failed to ensure temperatures of a fluid warmer cabinet was monitored and documented consistent with the facility's policy to ensure safe patient care. The findingsinclude:
    a. During a tour of operating room #2 (Labor and delivery) with RN #2 (clinical OperationManager) on 6/15/21 at 12:15PM observation of the fluid warmer and review of the fluidwarmer temperature log dated 6/1/21 to 6/15/21 failed to identified documentation the temperature for the fluid warmer cabinet was monitored and documented for five of the fifteen days reviewed.
    In an interview with Manager #2 on 6/15/21 at 12:30PM, Manager #2 indicated it was the expectation that temperatures of the fluid warmer cabinet were checked and documented daily. Manager #2 identified it was the responsibility of the Surgical technician to monitor the temperatures and complete documentation on the temperature log. Manager #2 indicatedthat when the surgical technician was not available it was the responsibility of the charge nurse to monitor the temperature and complete the log.
    Subsequent to the observation, Manager #2 indicated that an audit of the temperaturemonitoring of the fluid warmer cabinet would be initiated.
    Review of the Fluid/Blanket warming policy directed the temperature of the warming cabinets will be checked daily and entered into the log sheet. Any corrective actions will benoted and recheck will be performed one hour after corrective action.

Measures to prevent recurrence:
Effective 6/16/2021 to ensure consistent ownership, the day shift charge RN is assigned responsibility to sign off that temperatures of the fluid warmer cabinet are checked and documented. Beginning 6/16/2021 the Clinical Operations Manager for the Family Birthing Center informed all FBC staff of the day Charge RN requirement to ensure the temperature of the fluid warmer cabinet is checked and documented during daily huddles.
To ensure on-going compliance, the Director of FBC or designee will perform a weekly audit of the temperature log sheet to ensure daily sign-off. The audit results will be reported monthly to the Performance Improvement Safety Committee until three consecutive months of 100% compliance.

Effective date of correction action plan: 6/16/2021

Responsible person by title: Director Family Birthing Center

The following are violations of the Regulation of Connecticut State Agencies Section 19-13-D3 (h)Dietary Services and/or (i) General (6) and/or (k) Maternity service and/or (I) infection control (I).

10. Based on observations, review of facility documentation, review of policies, and interviews, the facility failed to ensure temperatures of the refrigerator used to store snacks for patients were monitored to ensure food safely, and failed to ensure a pantry refrigerator was maintained in a clean and sanitary condition. The findings include:
    a. During a tour of the Labor and Delivery, Recovery and Postpartum (LDRP)Unit with Manager #2 and RN #6 on 6/15/21 at 9:55AM observation of a pantry refrigerator whichcontained fifteen cartons of milk and bowl of individual sized coffee creamers failed to identify a thermometer located in the refrigerator.
    An interview with Manager #5 (Clinical Nutrition Manager) on 6/15/21 at 2:15PM indicated she was unable to explain the reason a thermometer was not located in the refrigerator. Also,Manager #5 stated she was unable to locate temperature logs with documented daily temperatures for the refrigerator. Manager #5 indicated it was the responsibility of the dietary Aide to stock the refrigerator and complete the temperature logs daily. Subsequent to the surveyor's observation, a thermometer was placed in the refrigerator andManager #5 stated that the issue of the missing thermometer would be investigated.
    Review of the Patient Food Service policy directed Food and nutrition Services personnel are responsible for daily temperature monitoring of unit refrigerators on floor stock sheets.
    b. A tour of the P 5 Unit of the Hospital and observation of the pantry with Manager #4 on 6/16/21 at 9:15AM identified the freezer that contained orange ice and ice cream had brownstains and debris. The refrigerator containing juices, sodas and coffee creamers was noted to have a dry yellow stain approximately 8 inches wide down the entire back wall of the refrigerator.

Also, four removable drawers located on the second self of the refrigerator as well as two drawers located in the lower section of the refrigerator had built- up, caked on brown residue and debris.
An interview with Manager #4 on 6/16/21 at 9:17PM identified that the dietary department was responsible for cleaning the pantry refrigerator.
In an interview with the Director of Food and Nutrition on 6/16/21 at 10:30PM identified that the Dietary Aide was responsible for checking refrigerator temperatures, rotate stock and clean the refrigerators daily. The Director indicated it was the expectation that pantry refrigerators were cleaned daily and stated the stains identified indicated the refrigerator and freezer were not cleaned consistent with the practice of the facility.
Review of the Patient Food Service policy directed catering associate is responsible to cleaning the refrigerators daily with a FDA approved germicide/disinfectant or general solutions (as appropriate) dispensed from approved dispensing system.

Measures to prevent recurrence:
Immediately on June 15, 2021 the missing thermometer was replaced. Effective June 22, 2021 during daily safety huddle the Director of Food and Nutrition re-enforced education with the catering associates on the *Nursing Unit Stock* policy. The following was added to the Par stock list for each catering associate to check:

- A working thermometer is present
- Take and document daily temperature
- Clean refrigerator daily and document
- Report any missing temperatures or temperatures not up to proper temperature to the manager on duty and document on par list

To ensure ongoing compliance on June 22, 2021 "monitor par stock list" was added to the opening and closing managers check list. The Director of Food and Nutrition or designee will perform a weekly audit of the manager's checklist to ensure the check list item is completed. The data from the audit will be reported monthly to the Performance Improvement Safety committee until three consecutive months of 100% compliance is achieved.

Effective date of correction action plan: 7/1/2021

Responsible person by title: Director of Food and Nutrition

Measures to prevent recurrence:
Immediately on June 15, 2021 the refrigerator was cleaned. Effective June 22, 2021 during daily safety huddle the Director of Food and Nutrition re-enforced education with the catering associates on the *Nursing Unit Stock* policy. The following was added to the Par stock list for each catering associate to check:

- A working thermometer is present
- Take and document daily temperature
- Clean refrigerator daily and document
- Report any missing temperatures or temperatures not up to proper temperature to the manager on duty and document on par list

To ensure ongoing compliance on June 22, 2021 "monitor par stock list" was added to the opening and closing managers check list. The Director of Food and Nutrition or designee will perform a weekly audit of the manager's checklist to ensure the check list item is completed. The data from the audit will be reported monthly to the Performance Improvement Safety committee until three consecutive months of 100% compliance is achieved.

Effective date of correction action plan: 7/1/2021

Responsible person by title: Director of Food and Nutrition

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (e)Nursing Services (1) and/or (g) Pharmacy and/or (i) General (6) and/or (I) infection control (1).

11. Based on observations, review of facility policies, and interviews, the Hospital failed to date an open multi use medication bottle and failed to discard expired saline solutions according to thefacility's policy. The findings include:
    a. A tour of the Labor and delivery Recovery and Delivery (LDR) unit and observation of themedication room with Manager #2, RN #5, and RN #6 on 6/15/21 at 10:15AM identified 1I opened undated bottle of Glycerin with approximately half of the contents. Also, observation was made of ten - 10 mil bottles of 0.9% normal saline with expiration date of 5/21.
    An interview with Manager #6 on 6/15/21 at 10:20AM identified that the Patient Care associates were responsible for checking and removing outdated solutions from the medication storage area. Manager #6 was unable to explain the reason expired medicationswere not discarded and was unable to identify when the container of glycerin was opened. In an interview with the interim Director of Pharmacy on 6/17/21 at 12:05PM identified thatstock bottles of glycerin were treated as multi vial and were good for 28 days after opened.Subsequent to the surveyor's observation, Manager #9 discarded the expired normal saline solutions and the bottle of glycerin.
    Review of the Hospital's Drug Storage policy directed all bulk floor stock medications should be stored as per the manufacture' s recommendations, any alterations in the manufacturer's container may result in a change in potency, and should be dated according to the packaging policy in the pharmacy manual. The Policy further directed that multi dosevials are good for 28 days after initial access.

Measures to prevent recurrence:
Beginning 6/16/2021 the Clinical Operations Manager for the Family Birthing Center reinforced with staff the policy for dating multiuse vials for 28 days after opening. Effective 6/16/2021 the Charge RN will be assigned the responsibility of completing a daily checklist to include checking and removing outdated solutions. In addition, beginning 6/25/2021, staff are required to read the *Multiple Dose Medication Vials* policy and attest to their understanding of the requirements to indicate the 28-day expiration date upon initial access as outlined in the policy.

To ensure on-going compliance, the Director of FBC or designee will perform a monthly audit ensuring multi-dose vials are accurately dated and solutions are not expired. The audit results will be reported monthly to the Performance Improvement Safety Committee until three consecutive months of 100% compliance.

Effective date of correction action plan: 7/12/2021

Responsible person by title: Director of Family Birthing Center

The following is a violation of the State of Connecticut Public Health Code Sectism 1 9-13-D3 ShortTerm_Hospitals, General and Special (a) Physical Plant (2) & (i) General (6).

12. During a tour of Waterbury Hospital on June 15, 2021 and subsequent documentation review, the following was observed:
    a. On 06/15/21 at various times throughout the day the surveyor, accompanied by the Directorof Biomedical Engineering & Facility Operations, observed that the facility failed to ensurethat all means of egress are maintained free of all obstructions and impediments to full and instant use in case of fire or any other emergency as required by section 14.4.1 of the Connecticut Fire Prevention Code. i.e; All exit access corridors in the basement area are being utilized for the storage of equipment, beds, furniture, tools, and cleaning supplies.

Measures to prevent recurrence:
Under the direction of the Director of Facilities, immobile items impeding egress in the basement were removed. On 6/21/2021 mobile shelfing to store supplies in the basement CS corridor were ordered. Beginning 6/22/2021 all supplies stored on skids in the CS basement corridors will be transferred to these mobile shelfing units to maintain proper egress. On 6/22/2021 immobile shelves in the CS corridor were removed. On 7/2/2021 vending machines were removed. To ensure ongoing compliance the Environmental Safety Officer or designee will perform weekly environmental rounding of the basement corridors to ensure proper egress. Audit results will be compiled monthly and reported to the Performance Improvement Committee until three consecutive months of 100% compliance is achieved.

Effective date of correction action plan: 7/2/2021

Responsible person by title: Environmental Safety Officer