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STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Healthcare Quality And Safety Branch

April 8, 2016

Alicia Caban, Center Manager
Planned Parenthood Of Connecticut Inc - Waterbury
969 West Main Street
Waterbury, CT 06702

Dear Ms. Caban:

An unannounced visit was made to Planned Parenthood Of Connecticut Inc - Waterbury on October 28, 2015 by a representative of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting a licensing 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 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 April 22, 2016 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.

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

Respectfully,

Loan D Nguyen
Loan Nguyen M.S.N., R.N., C.
Supervising Nurse Consultant
Facility Licensing and Investigations Section



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Affirmative Action/Equal Opportunity Employer

DATE(S) OF VISIT: October 28, 2015

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

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D48 Professional staff (b) (1) and/or 19-13-D51 Pharmaceuticals (3) and/or 19-13-D52 Maintenance.

1. Based on review of the agency documentation, surveyor observation and interview with agency personnel, the agency failed to maintain compliance with infection control and safety requirements. The findings include:

- a. During a tour of the agency with the Manager on 10/28/15, a multi-dose vial of Lidocaine 50ml for injection was found open, less than half full, stored in the medication refrigerator in the dirty utility room.

Interview and review of the surveyor observation with the Manager on 10/28/15 failed to identify the documentation on the vial of the date the vial was opened, and/or the date the vial should be discarded.

The agency policy on storage of multi-dose vials directed the documentation of the discard date as 28 days after opening, unless otherwise directed by the manufacturer;

During the tour of the agency on 10/28/15, the medication refrigerator was holding a vial of Hepatitis B vaccine, 20 doses of Fluvirin prefilled syringes, a syringe of Rho immune globulin, 10 vials of Gardasil, a vial of Lidocaine and a vial of Epinephrine.

Interview and inspection of the medication refrigerator with the Manager on 10/28/15 indicated that the medication refrigerator was stored in the dirty utility room under the sink counter where soiled equipment (speculums and probes) were washed, and under the counter holding the sterilizer, and failed to identify a clean and/or appropriate environment to store the medication refrigerator;

Interview and inspection of the medication refrigerator with the Manager on 10/28/15 identified two purple top blood specimen tubes containing blood used as quality control blood samples for the Rh factor testing device, and failed to identify the maintenance of quality control blood samples in a tightly sealed container in the refrigerator.



Planned Parenthood of Southern New England

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Handwritten notes:
Pac
7/29/16
Alicia Caban

June 28, 2016

Attached is the plan of corrective actions for the violation found during the unannounced inspection of the Waterbury Health Center on October 28, 2015.

1. Violation – Section 19-13-D48 Professional Staff (b) (1) and/or 19-13-D51 Pharmaceuticals (3) and or 19-13-D52 Maintenance.

a. Response – The Manager reviewed the policy and procedure for storage of pharmaceuticals – Administrative Chapter 7: Pharmaceuticals of the Manual of Standards and Guidelines, with staff at a staff meeting on November 3, 2015. The Manager is responsible for ensuring the policy and procedure are as followed.

During the tour it was found the medication refrigerator was stocked with medications and stored in lab refrigerator.

b. Response – The vial of Lidocaine that was found open was discarded on October 28, 2015. Vaccines including and not limited to, prefilled syringes and vials of Gardasil, Lidocaine and Rho immune globulin were moved from the lab refrigerator to a refrigerator in a clean and appropriate environment in the clinician workspace. These medications were moved on October 29, 2015.

During the interview and inspection of the medication refrigerator with the

Manager, two purple top blood specimen tubes were found containing blood used as quality control blood samples for Rh factor testing device and failed to identify the maintenance of quality control blood samples in a tightly sealed container.

c. Response - Purple top blood specimen tubes have been labeled as quality controls for Rh factor testing with expiration date and are now stored in a tight sealed container in the refrigerator in the dirty lab. An Advanced Clinical Assistant will monitor refrigerator temperature as well as medication storage. This change was effective October 29, 2015. The Manager is responsible for ensuring this process is followed.

I hope this plan of corrective actions answers the violation found during your visit of October 28, 2015. Please do not hesitate to contact me if you have further questions.

Best regards,
Alicia Caban - *Alicia Caban*
Center Manager - Waterbury