

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

August 23, 2018

Cassandra Lehr, Administrator
Hartford GYN Center
1 Main Street
Hartford, CT 06105

Dear Ms. Lehr:

Unannounced visits were made to Hartford GYN Center on July 6, 2018 by a representative of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting an investigation.

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 September 11, 2018 at 3:00 PM 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. Please be prepared to discuss those violations identified with an asterisk.

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 September 5, 2018 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.
4. 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.



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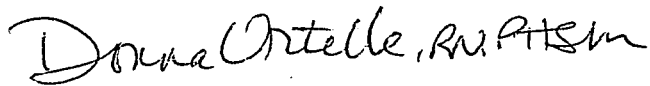


DATE(S) OF VISIT: July 6, 2018

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,

A handwritten signature in cursive script that reads "Donna Ortelle, RN, PHSM".

Donna Ortelle, RN, PHSM
Public Health Services Manager
Facility Licensing and Investigations Section

DMO:mb

DATE(S) OF VISIT: July 6, 2018

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The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D47
Governing Board, administrator (c).

1. Based on clinical record review, interview and policy review the facility failed to ensure that for three of three records reviewed that a physical was completed by a Licensed Independent Practitioner (LIP). The findings include the following:
 - a. Patient #1 presented to the clinic on 4/14/18 for an elective termination. Review of the clinical record indicated that the physical exam was completed on 4/14/18 at 9:36 AM that indicated that lungs were auscultated and were clear in all fields, apical pulse auscultated heart tones audible, regular, within normal limits. The record indicated that the physical was completed by the ultrasound technician (US Tech) tech.
 - b. Patient #2 presented on 5/12/18 for an elective termination. Review of the clinical record indicated that the physical exam was completed on 5/12/18 at 7:32 AM that indicated that lungs were auscultated and were clear in all fields, apical pulse auscultated heart tones audible, regular, within normal limits. The record indicated that the physical was completed by a registered nurse (R.N.).
 - c. Patient #3 presented on 6/2/18 for an elective termination. Review of the clinical record indicated that the physical exam was completed on 6/2/18 at 7:57 AM that indicated that lungs were auscultated and were clear in all fields, apical pulse auscultated heart tones audible, regular, within normal limits. The record indicated that the physical was completed by the US tech.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D50
Nursing Personnel.

2. Based on clinical record review, interview and policy review the facility failed to ensure that for one patient that the patient was assessed prior to discharge. The findings include the following:
 - a. Patient #1 presented to the clinic on 4/14/18 for an elective termination. A second trimester dilation and evacuation (D&E) was completed. The patient was brought to the procedure room at 1:27 PM, the procedure was started at 1:36 PM, and a time out was completed. The procedure was completed at 2:46 PM.
The PACU record indicated that the patient arrived to PACU at 2:55 PM and vital signs were obtained at 2:55 PM, 3:10 PM and 3:25 PM. The record indicated that at 3:10 PM and that the patient was in severe pain and received Vicodin two tablets at 3:10 PM, and Benadryl 50 mg IV over two minutes. The patient's level of pain was identified as mild at 3:25 PM. The Discharge note dated 4/14/18 at 4:35 PM indicated that the patient was able to ambulate to the bathroom, presented as alert and oriented with stable and pain 5/10. The record reflected the administration of Ibuprofen at 4:36 PM and failed to identify that a pre and/or post assessment of the patient's level of pain was completed. In addition the record failed to reflect further vital signs after 3:25 PM and/or prior to discharge. Review of the facility policy indicated that a registered nurses (RN) assessment will be completed on admission, every fifteen minutes post procedure and at discharge.

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The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D52 Maintenance.

3. Based on tour and observation the facility failed to ensure that a safe/ sanitary environment. The findings include the following:
 - a. Tour of the facility on 7/13/18 at 9:30 AM identified that the procedure tables in Procedure rooms #1 and 2 had tears and rips in the bottom portion of the table making it unable to be thoroughly cleaned and sanitized.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D50 Nursing Personnel.

4. Based on clinical record review, interview and policy review the facility failed to ensure that documentation in the clinical record of intravenous fluid administration was complete and/or accurate. The findings include the following:
 - a. Patient #1 presented to the clinic on 4/14/18 for an elective termination. The pre-procedure record indicated that an IV was inserted to the "left AC of saline" by the certified registered nurse anesthetist (CRNA). Review of the MD note indicated that it was a very difficult case, patients uterus pulled very high up due to a history of previous Cesarean section. The Patient also had a long cervix, only had an 11 extra-long suction cannula to use, fundal pressure was necessary throughout the case to bring the uterus close enough for extraction. A cervical laceration at 5 o'clock was on the cervix was repaired. Hemoglobin at the end of case was 9.5 (was 10.4 preop) and 1 liter of fluid with 20 units of Pitocin in it was administered. Review of the MAR indicated that 10 units of Pitocin were administered by the CRNA via IV at 2:37 PM. The medication administration record (MAR) failed to reflect the IV fluids/Pitocin administration.
 - b. The post anesthesia care unit (PACU) record indicated that the patient arrived to PACU at 2:55 PM and that the IV was intact. The notes further indicated that the IV was discontinued, the fluid intake section of the PACU record indicated "continued from OR". However, the record failed to reflect the time of removal and/or the type of fluids administered and/or the amount of fluids absorbed by the patient. The Discharge note dated 4/14/18 at 4:35 PM indicated that the patient was able to ambulate to the BR, presented as alert and oriented with stable vital signs and pain 5/10.
 - c. Patient #2 presented to the facility on 5/12/18. The record indicated that an IV was inserted at approximately 10:15 AM in the right antecubital. Review of the recovery room documentation indicated that the IV was intact. Although the documentation indicated that the IV was removed prior to discharge, the record failed to reflect the amount of fluid that was administered.
 - d. Patient #3 presented to the facility on 6/2/18. The record indicated that an IV was inserted in the left antecubital. Review of the recovery room documentation indicated that the IV was intact. Although the documentation indicated that the IV was removed prior to

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discharge, the record failed to reflect the amount of fluid that was administered.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D48 Professional staff (b)(4) and/or 19-13-D49 Records (b) and/or 19-13-D50 Nursing Personnel (c).

5. Based on review of the clinical records, review of policies and procedures and interviews with facility personnel for three of three patients reviewed (P #1, #2, and #3), the facility failed to ensure that documentation of clinical care was complete and/or accurate. The findings include:
 - a. Although the facility was previously cited for the failure to include staff titles after their signature in the clinical record and the plan of correction dated 1/27/18 indicated that staff titles would be included as of 3/20/18, review of the clinical record for three of three patients failed to reflect the presence of staff titles. For 3 of 3 patients who underwent a surgical procedure within the timeframe of 4/14/18 through 5/12/18 failed to reflect that documentation completed by registered nurse, medical assistants and/or ultra sound technician contained the credentials of the staff person. Review of the clinical records with the Director on 7/13/18 identified the staff member's titles with the staff member's name.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D48 (b)(2) and/or (4).

6. Based on clinical record review and policy review the facility failed to ensure that for 1 patient reviewed (P #1) that the consent form for anesthesia was completed by the LIP providing anesthesia and/or that for 2 of 2 records (P #1 and P #3) reviewed that the patient's level of sedation was documented. The findings include the following:
 - a. Review of Patient #1's clinical record indicated that the patient presented to the clinic on 4/14/18 for an elective termination. The pre-procedure record indicated that an IV was inserted by the certified registered nurse anesthetist (CRNA). The record indicated that the consent for intravenous (IV) sedation was signed by the facility counselor and the patient. Review of the IV sedation consent form obtained from the facility indicated that the CRNA should sign the consent form.
 - b. Patient #1's clinical record indicated that the patient received 800 mg of intravenous Diprovan during the period of 1:34 PM and 2:21 PM, the clinical record failed to reflect that patient's level of sedation. The facility policy indicated IV sedation is based on the clinical judgement of the anesthetist, however, does not address documentation of the level of sedation.
 - c. Patient #3's clinical record indicated that the patient received 450 mg of intravenous Diprovan during the period of 10:02 AM and 10:15 AM, the clinical record failed to reflect that patient's level of sedation.

Hartford Gyn Center - POC for VL dated 8/23/18

September 10, 2018

Donna Ortelle, RN, PHSM
410 Capitol Ave
PO Box 340308
Hartford, CT. 06134-0308

OK
HAE
9/26/18

Dear Donna Ortelle,

Thank you for sending me the report of our unannounced visit on July 6th, 2018. Please see the following plan of corrections and supporting documentation attached.

1a, 1b, 1c.

1. In accordance with our "History and Physical Examination" policy (updated 8/1/18 & attached), Hartford GYN Center will ensure that a practitioner will examine the patient immediately before their procedure. All practitioners have received and reviewed this policy. To ensure compliance with this policy, a random chart review was started on August 14th 2018 and will continue for 3 months, 10 charts a month will be reviewed. A monthly report of chart review findings will be made to the Governing Board to ensure compliance. ✓
2. August 13th, 2018.
3. Administrator.

2a.

1. Hartford GYN Center will ensure that all patients are assessed and discharged in accordance with our "Routine Post-Procedure Care in the Recovery Room" policy (attached). We will have a meeting with all nurses regarding our current policy and procedure for assessment and documentation of pain management and our policy and procedure for assessment and documentation of vital signs. To ensure compliance with this policy, a random chart review was started on September 16th 2018 and will continue for 3 months, 10 charts a month will be reviewed. ✓
2. September 15th, 2018.
3. Administrator.

3a.

1. Hartford GYN Center will replace the bottom portion of our procedure tables. If we are unable to replace the bottom portion, we will replace the entire table. ✓
2. October 31st 2018
3. Administrator.

4a, 4b, 4c and 4d.

1. Hartford GYN Center will ensure that the documentation of the type and amount of IV fluid will be in every chart. Hartford GYN Center will hold a meeting(s) with all CRNAs and nurses regarding the importance of this documentation. To ensure complete documentation, a random chart review will be done on 10 charts a month for three months starting September 15th, 2018. A monthly report of chart review findings will be made to the Governing Board to ensure compliance. ✓
2. September 15th, 2018.
3. Administrator.

5a.

1. Hartford GYN Center will continue to work with our EMR system to populate automatically the letters RN in signatures of registered nurses and MA in signatures of medical assistants when these individuals are documenting in EMR. In the interim, an in-service will be held with all RNs and MAs to reinforce the requirement of documenting RN, if a registered nurse, and MA, if a medical assistant, when documenting in EMR. To ensure complete documentation, a random chart review will be done on 10 charts a month for three months starting September 15th, 2018. A monthly report of chart review findings will be made to the Governing Board to ensure compliance. ✓
2. November 1st, 2018.
3. Administrator.

6a.

1. Hartford GYN Center has updated our IVS consent to include the CRNA's signature and updated all CRNAs of the need for their signature on this form. Please see "Consent to IV Sedation" attached. To ensure appropriate completion of this consent, a random chart review was started on August 14th 2018 and will continue for 3 months, 10 charts a month will be reviewed. A monthly report of chart review findings will be made to the Governing Board to ensure compliance. ✓
2. August 13th, 2018.
3. Administrator.

6b and 6c.

1. Hartford GYN Center will continue to ensure that all CRNAs provide procedural pain management in accordance with the HGC "Procedural Pain Management" Policy and with attention to complete and accurate documentation as noted in the approved Plan of Corrections submitted on February 27, 2018 and approved on March 27, 2018. A review of applicable regulations (including Section 19-13-D48(b)(2) and/or (4) does not contain a requirement for listing level of sedation in the record. As such, the Governing Board will continue to advise the CRNAs to document in accordance with all current policies. ✓
2. Current and on-going.
3. Administrator.