

REC'D MAY 27 2016

POC Approved 6/16/2016
Hallie

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FORM APPROVED

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AB0032	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B WING _____	(X3) DATE SURVEY COMPLETED 04/20/2016
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NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD OF CENTRAL NORTI	STREET ADDRESS, CITY, STATE, ZIP CODE 1765 DOBBINS ROAD CHAPEL HILL, NC 27514
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
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E 137	<p>.0305(A) Medical Records</p> <p>10A NCAC 14E .0305 MEDICAL RECORDS (a) A complete and permanent record shall be maintained for all patients including:</p> <ol style="list-style-type: none"> (1) the date and time of admission and discharge; (2) the patient's full and true name; (3) the patient's address; (4) the patient's date of birth; (5) the patient's emergency contact information; (6) the patient's diagnoses; (7) the patient's duration of pregnancy; (8) the patient's condition on admission and discharge; (9) a voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure witnessed by a family member, other patient representative, or facility staff member; (10) the patient's history and physical examination including identification of pre-existing or current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the procedure or anesthetic to be administered; and (11) documentation that indicates all items listed in Rule .0304(d) of this Section were provided to the patient. <p>This Rule is not met as evidenced by: Based on closed medical record review and staff interview clinic staff failed to ensure a properly executed informed consent signed by patient and physician was completed for 1 of 11 medical records reviewed (Pt #6).</p> <p>The findings include: Closed medical record review revealed Pt # 6 had</p>	E 137	<p>PPSAT requires that all physicians who perform abortions confirm patient informed consent. This is documented on the CO-015 NC Abortion Patient and Physician Informed Consent form. The Affiliate Medical Director will review this policy and procedure with all physicians by May 31, 2016 and the HCM or designee will monitor daily to ensure both patient and physician signatures are present on consent forms prior to the procedure. This monitoring will continue for a minimum of 3 months and until 100% compliance is achieved.</p>	5.31.16
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Division of Health Service Regulation
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

Penny Black

TITLE

CEO

(X6) DATE

5/26/2016

STATE FORM

6899

DDHB11

If continuation sheet 1 of 5

RECEIVED JUN 13 2016

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E 137	Continued From page 1 a medical abortion on 03/04/2016. Record review revealed a form signed by the patient titled "Client Information for Informed Consent Using the Abortion Pill", but failed to reveal the presence of the form "North Carolina Abortion Patient and Physician Informed Consent". Review failed to reveal an informed consent form signed by the patient and physician. Staff interview with Manager (Mgr) # 1 on 04/19/2016 around 1530 revealed Mgr # 1 reviewed the electronic record and there was no consent present for Pt # 6. Interview revealed "we should have a consent, signed by the physician, for every patient."	E 137	
E 159	.0312(A) Medications and Anesthesia 10A-14E .0312 (a) Medication (1) No medication or treatment shall be given except on written order of a physician. (2) Medications must be administered in accordance with the Nurse Practice Act of the State of North Carolina, and must be recorded in the patient's permanent record. This Rule is not met as evidenced by: Based on policy and procedure review, document review, closed medical record review, and staff and physician interview, clinic staff failed to completely document medication administration, specifically the times of administration for 5 of 11 clinic records reviewed. (# 1, #2, #4, #7, #11) The findings include:	E 159	Medications were given in accordance with standard medical protocol and the charts cited lacked complete documentation due to a recent shift to electronic medical records. Patient health and safety was not impacted by this incomplete documentation. The PPSAT EHR team has identified a method of documenting the time of administration for all medications administered in the course of abortion care, including documentation of initial dose of IV conscious sedation medications and of oral antibiotic. (See attached screen shots showing documentation as it appears within the template and on the final visit document.)

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NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD OF CENTRAL NORTH	STREET ADDRESS, CITY, STATE, ZIP CODE 1765 DOBBINS ROAD CHAPEL HILL, NC 27514
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E 159	<p>Continued From page 2</p> <p>Policy and Procedure review failed to reveal a policy that specified documentation requirements for medications administered.</p> <p>Review of "Skills Checklist: Recovery Room RN (Registered Nurse)" revealed "Skill/ Procedure... Documents medication correctly and completely in patient record. ..."</p> <p>1. Closed medical record review of Patient (Pt) # 1 revealed the patient had a surgical abortion on 04/15/2016. Review revealed Pt # 1 received Fentanyl Citrate (for analgesia, pain) 2 mls (milliliters, unit of measure) IV (intravenously), Ketorolac Tromethamine (anti-inflammatory, can treat pain) 1 ml IV, and 1 ml of Midazolam HCL (Hydrochloride) (used for preoperative sedation, to reduce anxiety, and produce amnesia [memory loss]) IV. Record review failed to reveal documentation of the times of medication administration for these drugs.</p> <p>Physician Interview on 04/19/2016 at 1515, with MD # 1 revealed there had been a change to computerized documentation and there were some documentation issues. Interview revealed there was not a space for charting the administration times of many medications. Interview revealed this was not acceptable and they would have to correct it.</p> <p>2. Closed medical record review of Pt # 2 revealed the patient underwent a surgical abortion on 04/01/2016. Review revealed Pt # 2 received Azithromycin (an antibiotic) 500 mg po (orally), Fentanyl Citrate 2 mls IV, Ketorolac Tromethamine 1 ml IV, and Midazolam HCL 1 ml IV. Review failed to reveal the times of administration.</p>	E 159	<p>All Chapel Hill nurses will be trained on this documentation prior to resumption of services in June, 2016. Nursing director will perform monthly audits of charts to confirm continued correct and complete documentation. This monitoring will continue for a minimum of 3 months and until 100% compliance is achieved.</p>	By June 2, 2016
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E 159	<p>Continued From page 3</p> <p>Physician Interview on 04/19/2016 at 1515 with MD #1 revealed there was no documentation for the administration times for these medications. Interview revealed there had been a change to computerized documentation and there was not a space for documenting the administration times of many medications. Interview revealed this was not acceptable and they would have to correct it.</p> <p>3. Closed medical record review of Pt #4 revealed the patient underwent a surgical abortion on 03/19/2016. Review revealed Pt #4 received Azithromycin, Fentanyl Citrate, Ketorolac Tromethamine, and Midazolam HCL. Review failed to reveal the times of medication administration.</p> <p>Physician Interview on 04/19/2016 at 1515, with MD # 1 revealed there had been a change to computerized documentation and there were some documentation issues. Interview revealed there was not a space for charting the administration times of many medications. Interview revealed this was not acceptable and they would have to correct it.</p> <p>4. Closed medical record review of Pt # 7 revealed the patient underwent a surgical abortion on 02/27/2016. Record review revealed the patient received Azithomycin 1 po and Ibuprofen 4 tablets by mouth in the office on 02/26/2016. Review revealed no times of administration were documented nor the name of the person administering. Further review revealed Pt #7 received Fentanyl Citrate, Ketorolac Tromethamine, and Midazolam HCL IV on 02/27/2016.</p> <p>Physician Interview on 04/19/2016 at 1515, with</p>	E 159	

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E 159	<p>Continued From page 4</p> <p>MD # 1 revealed there had been a change to computerized documentation and there were some documentation issues. Interview revealed there was not a space for charting the administration times of many medications. Interview revealed this was not acceptable and they would have to correct it.</p> <p>5. Closed medical record review of Pt # 11 revealed the patient underwent a surgical abortion on 04/16/2016. Record review revealed the patient received Azithromycin 500 mg po and Ibuprofen 800 mg po. Review failed to reveal the administration times for either medication.</p> <p>Physician Interview on 04/19/2016 at 1515, with MD # 1 revealed there had been a change to computerized documentation and there were some documentation issues. Interview revealed there was not a space for charting the administration times of many medications. Interview revealed this was not acceptable and they would have to correct it.</p>	E 159		

AZITHROMYCIN

Template View (medication grid):

Medication	Brand Name	Dose	Start Date	Stop Date	Sig	Rx Notes	NDC ID
AZITHROMYCIN	AZITHROMYCIN	500 mg	05/20/2016	05/21/2016	#1 po dispensed to pt. in clinic	Given at 8:47 AM by KH	00093716956

Visit Document:

Medications Prescribed during this visit

Medication	Dose	Sig	#Ord	Avail Refills	Ordered by	Transaction Category	Rx Notes
AZITHROMYCIN	500 mg	#1 po dispensed to pt. in clinic	1	0	Farris MD, Katherine	Administered	Given at 8:47 AM by KH

IV MEDICATIONS (FENTANYL, VERSED, TORADOL)

Template View (medication grid):

Medication	Brand Name	Dose	Start Date	Stop Date	Sig	Rx Notes	NDC ID
AZITHROMYCIN	AZITHROMYCIN	500 mg	05/20/2016	05/21/2016	#1 po dispensed to pt. in clinic	Given at 8:47 AM by KH	00093716956
MIDAZOLAM HCL	MIDAZOLAM HCL	2 mg/2 mL (1 mg/mL)	05/20/2016	05/21/2016	Administered via IV. May add additional doses as verbally ordered by MD		00641605710
FENTANYL CITRATE/PF	FENTANYL CITRATE	50 mcg/mL	05/20/2016	05/21/2016	Administered via IV. May add additional doses as verbally ordered by MD		00641602410
KETOROLAC TROMETHAMINE	KETOROLAC	30 mg/mL	05/20/2016	05/21/2016	Administered via IV.		00409379501

Template View (Sedation management):

Date/Time	O2	Propofol	Fentanyl	Nalbuphine	Other Analgesic	Versed	Other Anxiolytic	Methergine	Pitocin	Atropine	Iv Fluids	Bp	Pulse	Respiration	O2 Sat	LoC
05/20/2016 8:51 AM	4L/M		100mcg		ketorolac tromethamine 30mg	2mg						121/8	68	18	100%	
05/20/2016 8:56 AM	4L/M											120/8	77	18	100%	
05/20/2016 9:01 AM	4L/M					2mg						121/7	77	18	100%	
05/20/2016 9:06 AM	4L/M											121/8	77	17	100%	

Visit Document:

Medications

Medications Prescribed during this visit

Medication	Dose	Sig	#Ord	Avail Refills	Ordered by	Transaction Category	Rx Notes
AZITHROMYCIN	500 mg	#1 po dispensed to pt. in clinic	1	0	Farris MD, Katherine	Administered	Given at 8:47 AM by KH
FENTANYL CITRATE	50 mcg/mL	Administered via IV. May add additional doses as verbally ordered by MD	2	0	Farris MD, Katherine	Administered	
IBUPROFEN	800 mg	po administered to pt. in clinic	1	0	Farris MD, Katherine	Administered	
KETOROLAC TROMETHAMINE	30 mg/mL (1 mL)	Administered via IV.	1	0	Farris MD, Katherine	Administered	
MIDAZOLAM HCL	2 mg/2 mL (1 mg/mL)	Administered via IV. May add additional doses as verbally ordered by MD	1	0	Farris MD, Katherine	Administered	

Sedation Management:

Sedation Administration

Date/Time	BP	Pulse	Resp	O2 Sat	LoC	EBL	Pain Score	Nausea / Vomiting	Performed By
05/20/2016 9:06 AM	121/80	77	17	100					Kristine Holton
05/20/2016 9:01 AM	121/79	77	18	100					Kristine Holton
05/20/2016 8:56 AM	120/81	77	18	100					Kristine Holton
05/20/2016 8:51 AM	121/82	68	18	100					Kristine Holton

O2	Propofol	Fentanyl	Nalbuphine	Versed	Pitocin	Methergine	Atropine	IV Fluids
4L/M		100mcg		2mg				
4L/M				2mg				
4L/M								
4L/M								

Other Analgesic	Other Anxiolytic	MAC Changes	MAC Abn Comments	End Tidal CO2%
ketorolac tromethamine 30mg				

The above table is wrapped – the first line of each section is associated with the first time stamp, second line is the second timestamp, etc. We have a request in to our EHR vendor to have the date/time section repeat when the table wraps.