

REC'D SEP 21 2016

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FORM APPROVED

Maureen L. Kumara 10/10/2016

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: ab0015	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 08/18/2016
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NAME OF PROVIDER OR SUPPLIER A WOMAN'S CHOICE OF GREENSBORO	STREET ADDRESS, CITY, STATE, ZIP CODE 2425 RANDLEMAN RD GREENSBORO, NC 27406
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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 000 Initial Comments

E 000

An unannounced on site recertification survey was conducted on August 17 - August 18, 2016 to review the NC Rules Governing the Certification of Clinics for Abortions. Deficiencies were found in the areas of .0311(a) Surgical Services.

E 157 .0311(A) Surgical Services

E 157

10A-14E .0311(a) The procedure room shall be maintained exclusively for surgical procedures and shall be so designed and maintained to provide an atmosphere free of contamination by pathogenic organisms. The clinic shall establish procedures for infection control and universal precautions.

This Rule is not met as evidenced by:
Based on review of the facility's policy and procedures, observation and staff interview, the facility staff failed to discard expired medication and supplies, label medication vials and label prefilled syringes.

The findings included:

Review on August 17, 2016 of the policy and procedure revealed no formal policy for checking supplies expiration dates and discarding expired supplies and medications. Review on revealed no formal policy for labeling opened medication vials and labeling prefilled syringes.

1. Observation on August 17, 2016 at 1130 in the supply room revealed 2 boxes of size 7 - Criterion Surgeons Gloves with an expiration date of 4/16 (April, 2016) on the shelf. Observation revealed one box contained 50 packs of gloves and the

E157 #1
Criterion Surgeon Gloves size 7 with expiration date of 4/2016 quantity #67 packs were wasted upon verification of expiration.

Division of Health Service Regulation

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Selina Tate-Wall

Director of Patient Services

9-20-16

STATE FORM

6899

NP9011

If continuation sheet 1 of 5

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E 157	<p>Continued From page 1</p> <p>other contained 17 packs of gloves.</p> <p>Interveiw on August 17, 2016 at 1325 during tour with Staff #1, the Office Manager, revealed the expiration dates were not checked. Interview revealed she was responsible for ordering and checking expirations dates. Interview revealed the surgeons gloves would be discarded.</p> <p>2. Observation on August 17, 2016 at 1130 in Operating Room (OR) #2 revealed 10 packs of size 7 - Criterion Surgeons Gloves with an expiration date of 4/16 (April, 2016) on the shelf.</p> <p>Interveiw on August 17, 2016 at 1325 during tour with Staff #1, the Office Manager, revealed the expiration dates were not checked. Interview revealed she was responsible for ordering and checking expirations dates. Interview revealed the surgeons gloves would be discarded.</p> <p>3. Observation on August 17, 2016 at 1130 in Operating Room (OR) #1 revealed 6 packs of size 7 - Criterion Surgeons Gloves with an expiration date of 4/16 (April, 2016) on the shelf.</p> <p>Interveiw on August 17, 2016 at 1325 during tour with Staff #1, the Office Manager, revealed the expiration dates were not checked. Interview revealed she was responsible for ordering and checking expirations dates. Interview revealed the surgeons gloves would be discarded.</p> <p>Observation on August 17, 2016 at 1130 in Nurses station revealed two 5 ml (milliliter) vials of 0.1mg /ml Flumazanil (medication used to reverse the effects of narcotics) in the emergency cart. Observation revealed the medication expired 5/2016 (May 2016).</p>	E 157	<p>E157 #1 cont'd Corrective action policy in place (8/19/2016) for inventory received. Upon receipt of supplies, expiration dates will be checked by the Director of Patient Services. In the event, items are near expiring, they will be returned to the manufacturers. The Director of Patient Services will also perform an inventory check monthly to include a list of items that are near their expiration date.</p> <p>E157 #2 Criterion Surgeon Gloves size 7 with expiration date of 4/2016 quantity #10 packs were wasted by the Director of Patient Services upon verification of expiration.</p> <p>E157 #2 Corrective action policy in place (8/19/2016) for inventory received. Upon receipt of supplies, expiration dates will be checked. In the event, items are near expiring, they will be returned to the manufacturers. The Director of Patient Services will also perform an inventory check monthly to include a list of items that are near their expiration date.</p> <p>E157 #3 Criterion Surgeon Gloves size 7 with expiration date of 4/2016 quantity #6 packs were wasted by the Director of Patient Services upon verification of expiration.</p> <p>E157 #3 Corrective action policy in place (8/19/2016) for inventory received. Upon receipt of supplies, expiration dates will be checked. In the event, items are near expiring, they will be returned to the manufacturers. The Director of Patient Services will also perform an inventory check monthly to include a list of items that are near their expiration date.</p> <p>E157 #3 Flumazanil 0.1mg/ml vials with expiration date of 5/2016 quantity #2 vials were wasted by the Registered Nurse upon verification of expiration.</p>	
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E 157	<p>Continued From page 2</p> <p>Interview on August 17, 2016 at 1325 during tour with Staff #2, a Registered Nurse, revealed the expiration dates were not checked. Interview revealed she was responsible for ordering checking expirations dates. Interview revealed the medication would be discarded.</p> <p>4. Observation on August 17, 2016 at 1320 during tour in the nurses station revealed three filled 10 cc (cubic centimeters) syringes labeled lidocaine (numbing medication). Observation revealed there was no date or time of when the medication were drawn up, and, no initials indicating who drew it up. Further interview revealed the syringes contained a 9:1 Lidocaine and Sodium Bicarbonate mixture (9 parts lidocaine to 1 part sodium bicarbonate).</p> <p>Interview on August 17, 2016 during tour with Staff #1, the Office Manager, revealed the medication in the syringes were good for two days. Interview revealed the syringes and medication were discarded and new syringes were drawn up every two days. Interview revealed there were no documented competency for CMA's mixing or drawing up medications.</p> <p>Interview on August 17, 2016 during tour with staff #3, a Certified Medial Assistant (CMA), revealed she drew the medications up. Interview revealed the medications were drawn up two days ago. Interview revealed the doctor taught her how to mix the medication and draw it up. Interview revealed there was a card with the recipe for how to mix the medications. Interview revealed the medications should have been dated, timed and the initialed when the medication was drawn up.</p> <p>Interview with Staff #2, a Registered Nurse (RN),</p>	E 157	<p>E157 #3 Corrective action policy in place (8/19/2016) for BAYAN crash cart expiring medication and all other medication. In the event, items are near expiring, BANYAN will ship the new item to us. In return we will ship them the expired product. The Registered Nurse will also perform an inventory check monthly to include a list of items that are near their expiration date. The Director of Patient Services will monitor the inventory check to ensure that all medication and other items are within their expiration date.</p> <p>E157 #4 Corrective action policy in place (8/19/2016) by the Director of Patient Services. Labels will be affixed to syringes prior to drawing up medication by the CNA/CMA/RN. The label will include the date, time and initials of the staff who drew up the medication. Label will also include the recipe for the mixture "Lidocaine/Sodium Bicarbonate 10:1". The Director of Patient Services will monitor the competency of all staff to ensure that this protocol is followed.</p> <p>E157 #4 Staff will be trained by the Doctor on their competency to pre-draw syringes with Lidocaine/Sodium Bicarbonate Mixture. Competency will be signed off by the physician and monitored monthly by the Director of Patient Services to ensure quality assurance.</p> <p>E157 #4 Corrective action policy in place (8/19/2016) by the Director of Patient Services. Labels will be affixed to syringes prior to drawing up medication by the CNA/CMA/RN. The label will include the date, time and initials of the staff who drew up the medication. Label will also include the recipe for the mixture "Lidocaine/Sodium Bicarbonate 10:1". The Director of Patient Services will monitor the competency of all staff to ensure that this protocol is followed.</p>	
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E 157	<p>Continued From page 3</p> <p>revealed the prefilled medications were not labeled appropriately.</p> <p>Telephone interview on August 18, 2016 at 1230 with Staff #4, a doctor, revealed she confirmed competency by watching the CMA's draw up medication. Interview revealed the syringes should have been labeled with a date, a time and the initials of the person drew up the medication. Interview revealed CMA's were taught to do this, and, the syringes should have been labeled with the mixture in the syringes. Interview revealed the mixture of Lidocaine and Sodium Bicarbonate reduced burning and discomfort when injected.</p> <p>5. Observation on August 17, 2016 at 1320 during tour in the nurses station revealed two 50 cc (cubic centimeters) vials of Sodium Bicarbonate (baking soda solution) and one 50 cc vial of 1% Lidocaine (numbing medication) in a drawer. Observation revealed there was no date or time of when the medication was opened, and, no initials indicating who opened the medication.</p> <p>Interview on August 17, 2016 during tour with Staff #1, the Office Manager, revealed there was no documented competency for CMA's mixing or drawing up medications.</p> <p>Interview on August 17, 2016 during tour with staff #3, a Certified Medical Assistant (CMA), revealed she drew the medications up the prefilled syringes from the vials in the drawer. Interview revealed she could not recall when the vials were opened. Interview confirmed the vials were not dated, timed or initialed. Interview revealed the doctor taught her how to mix the medication and draw it up. Interview revealed there was a card with the recipe for how to mix the medications. Interview revealed she was able</p>	E 157	<p>E157 #4 Staff will be trained by the Doctor on their competency to pre-draw syringes with Lidocaine/Sodium Bicarbonate Mixture. Competency will be signed off by the physician and monitored monthly by the Director of Patient Services to ensure quality assurance..</p> <p>E157 #5 Corrective action policy in place (8/19/2016) by the Director of Patient Services. Labels will be affixed to syringes prior to drawing up medication by the CNA/CMA/RN. The label will include the date, time and initials of the staff who drew up the medication. Label will also include the recipe for the mixture "Lidocaine/Sodium Bicarbonate 10:1". The Director of Patient Services will monitor the competency of all staff to ensure that this protocol is followed.</p> <p>E157 #5 Staff will be trained by the Doctor on their competency to pre-draw syringes with Lidocaine/Sodium Bicarbonate Mixture. Competency will be signed off by the physician and monitored monthly by the Director of Patient Services to ensure quality assurance..</p> <p>E157 #5 Corrective action policy in place (8/19/2016). Labels will be affixed to vials by the CNA/CMA/RN prior to opening. The label will include the date, time and initials of the staff who opened up the medication. Label will also include the date shelf life will be reached. The Director of Patient Services will monitor the competency of all staff to ensure that this protocol is followed.</p>	
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E 157	<p>Continued From page 4</p> <p>to describe the process used for withdrawing medication from the vials and mixing them. Interview revealed Staff #3 was able to describe the process used for drawing up a prefilled syringe.</p> <p>Interview on August 17, 2016 during tour with Staff #2, a Registered Nurse (RN), revealed the vials were not labeled appropriately.</p> <p>Telephone interview on August 18, 2016 at 1230 with Staff #4, a doctor, revealed she confirmed competency by watching the CMA's mix the medication and draw it up into a syringe. Interview revealed CMA's were taught to do this, and, the vials and the syringes should have been appropriately labeled with the medication mixture, the date, the time and the initials of the person who drew up the medication.</p>	E 157	<p>E157 #5 Corrective action policy in place (8/19/2016). Labels will be affixed to vials by the CNA/CMA/RN prior to opening. The label will include the date, time and initials of the staff who opened up the medication. Label will also include the date shelf life will be reached. The Director of Patient Services will monitor the competency of all staff to ensure that this protocol is followed.</p> <p>E157 #5 Staff will be trained by the Doctor on their competency to pre-draw syringes with Lidocaine/Sodium Bicarbonate Mixture. Competency will be signed off by the physician and monitored monthly by the Director of Patient Services to ensure quality assurance.</p>	
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