LICENSURE UNIT

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FORM APPROVED

Nebraska DHHS Licensure Unit

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	HC001	A. BUILDING: ______ B. WING ______	C 08/06/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BELLEVUE HEALTH CENTER	1002 WEST MISSION BELLEVUE, NE 68005

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G 150	7-006.06 Patient Care and Treatment Each health clinic must establish and implement written policies and procedures that encompass all care and treatment provided to patients. The policies and procedures are consistent with prevailing professional standards, delineate the scope of services provided in the health clinic and encompass aspects to protect the health and safety of patients. This Standard is not met as evidenced by: Based on observation, staff interview and policy review; the facility failed to have a policy in place to consistently identify tissue specimen(s) removed during the abortion procedure (extraction of fetal tissue from the uterus) that were stored in the freezer. Five of Five specimens in the freezer were not consistently identified. This procedure had the potential to effect any tissue specimen(s) stored by the facility. Findings are: A. During the facility tour on 8/4/15 from 12:00 PM to 1: 20 PM; the freezer (which had been identified for storage of tissue specimens) was observed to have five tissue specimen(s) with the following identification: -Specimen 1-- A tissue specimen wrapped in a chux (a water impermeable pad) placed in a plastic bag identified with initials and a date written with a magic marker; -Specimen 2-- A tissue specimen wrapped in a chux placed in a plastic bag identified with a first initial, last name and a patient number written with a magic marker; -Specimen 3-- A tissue specimen wrapped in a chux placed in a plastic bag identified with the words 'room 1 specimen' and the date written	G 150	**G 150 7-006.06 A.** Specimen 1-5 were all disposed of in red biohazard bags and in biohazard box in garage. The DON will be responsible for Checking the freezer monthly.	08/04/15

Licensure Unit

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: M L Carhart

TITLE: Clinic Administrator

(X6) DATE: 09/18/2015

approved - EM

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G 150	Continued From page 1 with a magic marker; - Specimen 4-- A tissue specimen wrapped in a chux placed in a plastic bag identified with a first name, last name and the date written with a magic marker; and - Specimen 5 -- A tissue specimen wrapped in a chux placed in a plastic bag without any identifying information such as a name, number or date written on the bag. B. An interview with the Director of Nurses [DON] during the tour on 8/4/15 from 12:00 PM to 1:20 PM revealed, that there needed to be a better system for identification of the specimens in the freezer. The DON identified that there was not a specific policy or procedure in place for labeling and identifying specimens placed in freezer for hold. C. Per a written response as part of the physician interview dated 8/13/15, the sole exception to the disposal of tissue via protocol for the certified medical waste disposal company pick up would be: "a) A request from a referring provider to have the tissue forwarded to a laboratory for further diagnostic study. b) A request from a law enforcement agency or jurisdiction to have the tissue surrendered to an agent for evidence. c) A request from the patient to have the tissue released to a licensed funeral director or a agent to prepare the fetus for cremation or burial." D. Review of the facility Policy and Procedure Manual, Section 8 -Procedure Manual: Identification of Products of Conception (POC) revealed the following information: "...If the POC was a result of rape, it will be put in sterile specimen cup, labeled and placed in the	G 150	**G 150 7-006.06 B-D** The policy for Products of Conception has been updated. See Attachments 1-3 **G 150 7-006.06 D** Amendment to Dr. Carhart's Response. See Attachment 24	08/07/15

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G 150	Continued From page 2 freezer." The Policy and Procedure Manual lacked any further protocol regarding the identification and management of frozen tissue specimens.	G 150		
G 410	7-006.09E Storage of Drugs/Devices/Biologicals All drugs, devices, and biologicals must be stored in secured areas and stored in accordance with the manufacturer ' s, distributor ' s, packager ' s, or dispensing pharmacist ' s instructions for temperature, light, humidity, and other storage instructions. Only authorized personnel, designated by policy and procedure of the health clinic as responsible for administration, provision, or dispensing, must have access to drugs, devices, and biologicals. The supply of drugs, devices, and biologicals must be protected and restricted to use for legally authorized purposes and must be checked on a regular basis to ensure expired, mislabeled, unlabeled, or unusable products are not available for patient use. This Standard is not met as evidenced by: Based on observation and staff interview; the facility failed to ensure that expired biologicals were not available for patient use. Two of Two exam room cupboards contained boxes of Lamicel Osmotic Cervical Dilators and Laminaria Tents [a thin rod of dried kelp that is placed into the cervix (the "neck" of the uterus) to soften and dilate (open) the cervix prior to the abortion procedure (extraction of fetal tissue from the uterus)]. [Each box contained 20-24 Cervical Dilators in individualized pouches.] This had the potential to effect all patients requiring the use of this product for an abortion procedure.	G 410		

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G 410	Continued From page 3 Findings are: A. Observations made on the facility tour 8/14/15 from 12:00 PM to 1:20 PM revealed the following: 1) Exam Room 1 had a cupboard that contained multiple boxes of Lamicel Osmotic Cervical Dilators and Laminaria Tents. The following boxes of Laminaria/Lamicel Osmotic Cervical Dilators were outdated: -5 boxes of 4 mm (millimeter long) / 70 mm (millimeter diameter) Laminaria Tents which were outdated 9/2014 and 1 box that was outdated 11/2013; -1 box of 2 mm / extra small Laminaria Tents with an outdate of 1/2014 and 1 box that outdated 7/2015; -1 box of 6 mm / 70 mm Laminaria Tents with an outdate of 12/2011; 4 boxes that outdated 7/2014; and 1 box that outdated 7/2015; -1 box of 3 mm / (no other mm listing on box related to diameter) of Lamicel Osmotic Cervical Dilators with an outdate of 8/2005; 1 box with an outdate of 10/2005; 1 box with an outdate of 5/2008 and 1 box with an outdate of 7/2008; and -2 boxes of 5 mm / (no other mm listing on box related to diameter) of Lamicel Osmotic Cervical Dilators with an outdate of 7/2008 and 1 box outdated 12/2003. 2) Exam Room 2 had a cupboard that contained multiple boxes of Laminaria Tent. The following boxes of Laminaria were outdated: -1 boxes of 4 mm (millimeter long) / 70 mm (millimeter diameter) Laminaria Tents with an outdate of 11/2013; -1 box of 2 mm / extra small Laminaria Tents with an outdate of 3/2014; and -1 box of 8 mm / 70 mm Laminaria Tents with an	G 410	**G 410 7-006.09E A1-2** All expired supplies were disposed of properly. The DON will check for expiration dates monthly	08/04/15

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G 410	Continued From page 4 outdate of 2/2015. B. Staff interview (during the tour on 8/4/15 from 12:00 PM to 1:20 PM) with the Director of Nurses for the clinic revealed, "I do monthly checks to check for expired medications, but didn't realize that those had outdated."	G 410	**G 410 7-006.09E** New policies written for supplies. See Attachments 4-5	08/07/15
G 530	7-006.15B Equipment, Fixtures, and Furnishings The facility must provide and maintain all equipment, fixtures, and furnishings clean, safe and in good repair. 7-006.15B1 The facility must establish and implement a process designed for routine and preventative maintenance of equipment and furnishings to ensure that such equipment and furnishings are safe and function to meet the intended use. This Standard is not met as evidenced by: Based on observation and staff interview; the facility failed to: 1)establish preventative maintenance processes for 7 of 10 sampled pieces of medical equipment (2 ultrasound machines - medical equipment that uses sound waves to produce images of what is going on inside the body; 2 defibrillator/cardiac monitors - used only for monitoring the rhythm of the heart; 1 cautery machine - an instrument used to cut and repair tissue; 2 suction machines - a machine which has a tube that provides suction to removed tissue or fluid from the body) and 2) implement preventative maintenance for 3 of 10 sampled pieces of medical equipment (3 autoclaves - a machine that sterilizes medical instruments in between patient use). This failed practice has the potential to affect all patients receiving surgical procedures at the clinic.	G 530		

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G 530	Continued From page 5 Findings are: A. A tour of the clinic on 8/4/15 from 12:00 PM to 1:20 PM; revealed the following medical equipment with no evidence of preventive maintenance on the equipment: -Procedure Room 1 - ultrasound machine, defibrillator/cardiac monitor, suction machine, and cautery machine; -Procedure Room 2 - ultrasound machine, defibrillator/cardiac monitor, and suction machine. Interview with the Director or Nursing (DON) on 8/4/15 from 12:00 PM to 1:20 PM (during the tour) indicated that no one provided preventive maintenance on the above equipment. B. A tour of the clinic on 8/4/15 from 12:00 PM to 1:20 PM; revealed 3 autoclaves in the center sterilization room. The DON provided a 3-ring note book that contained log sheets titled '2015 Autoclave' for each autoclave machine. The log sheets contained an area for documenting completion of weekly, monthly and Maxi Test maintenance (a test that is completed to make sure the sterilizer is working properly). The following directions were listed at the bottom of the log sheets: "Please initial and date when completed." The log sheet for each of the 3 autoclaves only contained initials on the weekly log for January 2015. All other areas on the form were blank. C. Interview with the DON on 8/6/15 from 9:50 AM to 10:10 AM revealed that the clinic lacked a policy and procedure for preventive maintenance on equipment. Interview with the Clinic Manager 8/6/15 from 11:15 AM to 11:45 AM revealed that the clinic had no scheduled preventive	G 530	**G 530 7-006. 15B A-C** All machines have been maintenance according to Owner Manuals that have been located online or through the manufacturer. New policies written for Machine Maintenance. The DON will check the logs monthly. See Attachments 6-23	08/24/15 08/24/15

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G 530	Continued From page 6 maintenance for the medical equipment.	G 530		