OHIO DEPARTMENT OF HEALTH

246 North High Street
Columbus, Ohio 43215

614/466-3543
www.odh.ohio.gov

John R. Kasich / Governor

JUL 3 0 2014

David Burkons, MD
Northeast Ohio Women's Center, Inc.
1611 South Green Road, Suite 004
South Euclid, Ohio 44121

Dba Northeast Ohio Women's Center
2127 State Road
Cuyahoga Falls, Ohio 44223

Re: Proposal to Deny License
ID # 1081 AS

Dear Dr. Burkons:

You are hereby notified that I propose to issue an Order denying Northeast Ohio Women's Center, Inc.'s application for a health care facility license (ambulatory surgical facility) to operate Northeast Ohio Women's Center at 2127 State Road, Cuyahoga Falls, Ohio. This action is taken pursuant to Revised Code (R.C.) 3702.30(D) and Ohio Admin. Code 3701-83-05(C)(2) due to violations of R.C. 3702.30(D) and Ohio Administrative Code 3701-83 as outlined in the attached survey report, which is hereby incorporated into this letter. These violations serve as the basis for my proposed denial of your license application.

You may request a hearing before me or my duly authorized representative concerning my proposal to deny Northeast Ohio Women's Center's application for a health care facility license. Such request must be made in writing and received within thirty (30) days of receipt of this letter and should be directed to Kaye Norton, Ohio Department of Health, 246 N. High Street, Office of the General Counsel, Columbus, Ohio, 43215. A request is considered timely if it is received by ODH

An Equal Opportunity Employer/Provider

via FAX, hand delivery, or ordinary United States mail, within thirty days of the date of receipt of this letter.

At a hearing, you may appear in person or be represented by an attorney. You may present evidence and you may examine witnesses for and against you. You also may present your position, contentions, or arguments in writing, rather than appear in person for a hearing. If you are a corporation or limited liability corporation, you must be represented by an attorney licensed to practice in Ohio. Please be advised that if you do not request a hearing within thirty days of receipt of this letter, I may deny Northeast Ohio Women's Center's application for a health care facility license.

Please contact Heather Coglianese, Assistant Counsel, at (614) 466-4882, if you have questions about this matter.

Sincerely,

Lance D. Himes
Interim Director of Health

CMRRR: 7011 2970 0001 8004 0499

Cc: Tamara Malkoff, Chief, Bureau of Information & Operational Support
Drema Phelps, Chief, Bureau of Community Health Care Facilities & Services
Heather Coglianese, Office of General Counsel
Jennifer Branch, Attorney for Northeast Ohio Women's Center, Inc.

Ohio Dept Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	1081AS	A. BUILDING: ______ B. WING ______	02/03/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTHEAST OHIO WOMEN'S CENTER	2127 STATE ROAD CUYAHOGA FALLS, OH 44223

(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
C 000	Initial Comments Initial Licensure Compliance Inspection Administrator: Lindsay Marrone County: Summit Number of ORs: 1 The following violations are issued as a result of the initial licensure compliance inspection completed on 02/03/13.	C 000		
C 104	O.A.C. 3701-83-03 (F) Governing Body The HCF shall have an identifiable governing body responsible for the following: (1) The development and implementation of policies and procedures and a mission statement for the orderly development and management of the HCF; (2) The evaluation of the HCF's quality assesment and performance improvement program on an annual basis; and (3) The development and maintenance of a disaster prteparedness plan. This Rule is not met as evidenced by: Based on review of governing body minutes and	C 104		

Ohio Department of Health
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE — (X6) DATE

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C 104	Continued From page 1 staff interview, the governing body lacked a plan to evaluate the facility's quality assessment and improvement program (QAPI) on an annual basis. This could potentially affect all patients in the facility. Findings include: On 02/03/14, a review of the governing body minutes revealed there was no discussion or plan to review the facility's QAPI program annually. This was verified with Staff B at 2:15 PM on 02/03/14.	C 104		
C 123	O.A.C. 3701-83-08 (E) Staff Orientation & Training Each HCF shall provide an ongoing training program for its staff. The program shall provide both orientation and continuing training to all staff members. The orientation shall be appropriate to the tasks that each staff member will be expected to perform. Continuing training shall be designed to assure appropriate skill levels are maintained and that staff are informed of changes in techniques, philosophies, goals, and similar matters. The continuing training may include attending and participating in professional meetings and seminars. This Rule is not met as evidenced by: Based on personal file review, policy review, and staff interview the facility failed to provide orientation to staff (5 of 5 nursing staff). This has the potential to affect the safety of all patients	C 123		

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C 123	Continued From page 2 who receive surgical procedures from the facility. Findings include: Review of Staff B, C, D, E, and F's personal files completed on 02/03/14 revealed orientation was not completed. Interview with Staff A completed on 02/03/14 at 9:00 AM revealed that none of the staff have been officially hired due not wanting them to quit their other positions. "The staff have already had some training like their Advance Cardiac Life Support, but not all of it." Staff A also stated that fire drills have not been completed with staff at this time but can if it needs to be done. Review of the New Employee Information document completed on 02/03/14 revealed upon hire staff will be scheduled for a new employee orientation meeting. During the meeting the staff will receive important information about the company's policies and procedures.	C 123		
C 151	O.A.C. 3701-83-12 (B) Q A & Improvement Plan Each HCF shall develop a written plan that describes the quality assessment and performance improvement program's objectives, organization, scope, and mechanism for overseeing the effectiveness of monitoring, evaluation, improvement and problem-solving activities. This Rule is not met as evidenced by: Based on review of policy and procedures and	C 151		

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NAME OF PROVIDER OR SUPPLIER: NORTHEAST OHIO WOMEN'S CENTER

STREET ADDRESS, CITY, STATE, ZIP CODE: 2127 STATE ROAD, CUYAHOGA FALLS, OH 44223

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C 151	Continued From page 3 staff interview, the facility lacked a written plan for a quality assessment and improvement program (QAPI). This could potentially affect all patients in the facility. Findings include: On 02/03/14, a review of facility policies and procedures revealed there was no written QAPI plan for monitoring and evaluating all aspects of care. This was verified with Staff B at 2:10 PM on 02/03/14.	C 151		
C 222	O.A.C. 3701-83-18 (C) Director of Nursing Each ASF shall have a director of nursing who is an RN with experience in surgical and recovery room nursing care. The director of nursing shall be responsible for the management of nursing services. This Rule is not met as evidenced by: Based on interview and review of the organizational flow chart no Director of Nursing was noted. This could potentially affect all patients receiving surgical procedures from this facility. Findings include: Review of the Organizational Flow Chart completed on 02/03/14 revealed no Director of Nursing was listed. Interview with Staff B completed on 02/03/14 at 10:52 AM revealed the facility did not really have a Director of Nursing at this time. But if they did it	C 222		

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C 222	Continued From page 4 would be Staff C but he/she does not know yet.	C 222		
C 231	O.A.C. 3701-83-19 (B) Drug Control & Accountability The ASF shall: (1) Provide adequate space, equipment, and staff for storage and the administration of drugs in compliance with state and federal laws and regulations. (2) Establish and implement a program for the control and accountability of drug products throughout the facility and maintain a list of medications that are always available. This Rule is not met as evidenced by: Based on observations, staff interview, and policy review, the facility failed to ensure there were no expired drugs and biologicals in the facility. This has the potential to affect all patients in the facility. Findings include: A tour was conducted in the facility with Staff B between 9:50 AM and 10:30 PM. The following medications were observed expired: 1. The hallway medication cabinet, located by the eye wash station, was observed with one 50 milliliter (ml) vial of Lidocaine HCL, which contained a handwritten date of 01/18/13 and initial of a staff member from the previous employer. Staff B stated this vial was left over from the previous owner.	C 231		

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C 231	Continued From page 5 This cabinet also contained 4 unopened 50 ml vials of the same medication. The expiration dates on these vials were 02/01/14. The cabinet also contained three 20 ml vials and one 10 ml vial each of sodium chloride solution which contained expiration dates of 10/13. 2. The supply room was observed with an outdated box of one-Step urine Hcg pregnancy test strips. The box was observed full of test strips. The expiration date on the container was 04/13. 3. The operating room was observed with a container of lubricant which had expired prior to this date of 02/03/14. These expired medications and supplies were verified with Staff B during tour.	C 231		
C 244	O.A.C. 3701-83-20 (E) Emergency Power Each ASF shall have emergency power available in operative, procedure, and recovery areas. This Rule is not met as evidenced by: Based on tour and staff verification the facility failed to have emergency power available in operating room. This could potentially affect all patients in the facility. Findings include: Tour of the facility completed on 02/03/14 at 10:30 AM revealed no emergency battery backup lighting in the operating room and the recovery	C 244		

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C 244	Continued From page 6 room. Interview with Staff B completed on 02/03/14 at 10:40 AM revealed they do have flash lights available in all rooms for staff during an emergency.	C 244		