

**CERTIFICATION SURVEY PROCESSING CONTROL SHEET
NON LONG TERM CARE UNIT (NLTC)**

PHONE: (614) 387-0801 FAX: (614) 564-2475

OHIO DEPT OF HEALTH
DQA BCHKFS

SURVEY HEALTH ENTRANCE	DATE: 2/3/14	2014 FEB -6 AM 10:44
SURVEY HEALTH EXIT	DATE: 2/3/14	
LSC EXIT	DATE: _____	
MAILED/TURNED IN	DATE: 2/4/14	
FISCAL YEAR	10/31	

PSR TO BE A DESK AUDIT? Yes No

Action (circle): LIC 1666 **INITIAL** CERTIFICATION VALIDATION COMPLAINT PSR (Onsite/Desk Audit)

COMPLAINT(S) # _____

TYPE (circle): **ASC** CAH CORF ESRD HHA HOSPICE HOSPITAL EMTALA PTIP REHAB

PPS (PSYCH/REHAB) RHC X-RAY TRANSPLANT

CCN/LIC: 1081AS

YXLNII

FACILITY NAME: NE Ohio Womens Center

ADDRESS: 2127 State Rd

CITY/COUNTY/ZIP Cuyahoga Falls / Summit 44223

Surveyor Initials	Oscar #	Tag #	Check if Condition	Check if Waiver	Recited	Oscar #	Tag #	Check if Condition	Check if Waiver	Recited
UR 03245	03245	C104								
EA 31007	31007	C123								
	03245	C151								
	31007	C222								
	03245	C231								
	31007	C244								

NLTC/Lic Cert Entered (Date/Initials) CERT 2-6-14 10/60 10/45 CONDI 5/30 PSR LIC 10/30 PSR 5/15 PSR

Draft To Supervisor By OA (Date/Initials) 2-6-14 LTR. Signed (Date/Initials) _____

SOD MAILED (Date/Initials) _____

2567 2567B 1601 1601B LTR GUIDE 1602 1666/CMS LOG CALENDAR ACO Lic Cert
To ACTS (Date/Initials) _____

POC Due 5 Days or 10 Days _____ LOG CALENDAR ACO Lic Cert
POC Approved (Date/Initials) _____ File To Pending Drawer (Date/Initials) _____

File To Review (Date/Initials) _____ LOG Lic Cert

670 Completed (Date/Initials) 8-1-14 BS All Final Info Entered Into Lic Cert (Date/Initials) _____

LIC LTR CMS NO DEF. LTR TO MAUST _____

File To Central Office (Date/Initials) _____ LOG ACO Lic Cert

NOTES: CLOSED IN ASPEN Date/Initials _____

Easley, Genell

From: LicCert@odh.ohio.gov
Sent: Monday, December 16, 2013 10:39 AM
To: McCann, Debra; Iacovetta, Wanda; Ellis, Lucinda; Slaggy, Bev; Uhl, Tracy; Richey, Shannon; Easley, Genell
Cc: DQA Certification & Licensure; Summers, Steve
Subject: 1081AS NORTHEAST OHO WOMEN'S CENTER - New Application

This e-mail confirms 1081AS NORTHEAST OHO WOMEN'S CENTER is ready for their initial inspection.

Easley, Genell

From: liccert@odh.ohio.gov
Sent: Monday, December 16, 2013 12:03 PM
To: Goodwin, Adria; Smith, Bridgette; Valentine, Charlene; mary.lucas@odh.ohio.gov; Dunn, Steven; Cahill, Cara; McCann, Debra; Iacovetta, Wanda; Ellis, Lucinda; Slaggy, Bev; Uhl, Tracy; Richey, Shannon; Easley, Genell
Cc: DQA Certification & Licensure; Summers, Steve; DQA Certification & Licensure; Summers, Steve
Subject: Application Document: 1081AS NORTHEAST OHO WOMEN'S CENTER - Document Uploaded For New Application

This notification is being sent from the Ohio Department of Health Certification and Licensing system because a new document has been uploaded for:

Facility: OHL41753 1081AS NORTHEAST OHO WOMEN'S CENTER

Application: New Application

Document Description: Licensure Packet

Please view this document at:

http://odhgateway.odh.ohio.gov/certlicensure/show_letter.aspx?id=178393&doc=318890

You can view ALL documents at: <http://odhgateway.odh.ohio.gov/certlicensure/default.aspx>

CV

Health Care Facility Licensure Application

As defined in section 3702.30 of the ORC and 3701-83-04 of the OAC

30000

ODH Use Only ID # <u>1091AS</u> OHL # <u>41753</u>
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Print Legibly in Ink or Type

1. Application Type <input checked="" type="checkbox"/> Initial <input type="checkbox"/> Change of Ownership <input type="checkbox"/> Initial/Replacing existing facility, ID # _____	2. Date of operation or projected opening date or date of change of ownership. _____/_____/_____
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3. Licensure Type - only one

<input checked="" type="checkbox"/> Ambulatory surgical facility # of operating rooms <u>1</u> # of procedure rooms _____ Is this facility located in a building that houses in-patient care? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Freestanding dialysis center # of hemodialysis stations _____ # of peritoneal stations _____
<input type="checkbox"/> Freestanding inpatient rehabilitation facility # of patient care beds _____	<input type="checkbox"/> Freestanding birthing center # of birthing rooms _____

4. Facility name (DBA) <u>Northeast Ohio Womens Center</u>	Telephone number <u>(216) 403-6448</u>
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6. Previous facility name, if applicable

7. Address
2127 State Rd

City <u>Cuyahoga Falls</u>	Zip <u>44223</u>	County <u>Summit</u>
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8. E-mail address
olmburkens@aol.com

9. Mailing address, if different from above

Name		
Address		
City	State	Zip

10. Days and hours of operation for this facility

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
A.M.	<u>11</u>		<u>11</u>		<u>10</u>	<u>9-12</u>	
P.M.		<u>5-12-6</u>	<u>5</u>	<u>12-6</u>	<u>5</u>		

3212

11. Is this health care facility accredited or certified? No Yes
 If yes, type _____
 If yes, enclose a copy the current accreditation inspection report with this application.

12. This business is a/an Individual Partnership Limited Liability Company
 Corporation Association Other: _____

Individual owner: Skip questions 19 through 29 **only**.

More than one owner, partnership, corporation, limited liability company or association, skip questions 13 through 18 **only**.

13. Owner's name _____

14. Address _____

City	State	Zip
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15. Phone number	16. Owner's occupation
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17. Owner's business address, if different from question #7

Address _____

City	State	Zip	18. Phone number ()
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Multiple Owners, Partnership, Limited Liability Company, Corporation, Association, Other

19. Business entity name
Northeast Ohio Women's Center, Inc

20. Address
1611 S. Green Rd #004

City <i>S. Euclid</i>	State <i>Ohio</i>	Zip <i>44121</i>	21. Phone number <i>(26) 297-2061</i>
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22. Business Activity
Abortion Clinic

23. This business is a <input checked="" type="checkbox"/> For profit <input type="checkbox"/> Not for Profit <input type="checkbox"/> Government	24. Date of incorporated or registration <i>11, 8, 2013</i>	25. Charter/registration number <i># 2244317</i>
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26. List the **name of each person** who has an ownership interest of 5% or more in the business (attach additional sheets if necessary).

Name <i>David M. Burkens, MD</i>	Name
Name	Name
Name	Name

27. Officers names, titles, addresses and phone numbers

Title	Name	Address	Phone Number
Owner	David M. Burkens, M.D.	1611 S. Green Rd Hood S, Bucled, Ohio 44122	216-403-6448 (e) (216) 297-2061
			()
			()
			()

28. Statutory agent's name	Address	Phone Number
David M. Burkens, M.D.	1611 S. Green Rd Hood S, Bucled, Ohio 44122	216-403-6448 (216) 297-2061

29. If state agency or local government, the name, address and phone number of individual authorized to enter into agreement on behalf of state agency or local government. Not Applicable

Name	Address	Phone Number
		()

30. On-site administrator's name	
31. Medical director's name or individual responsible for the provision of health care services	32. License/Certification #

33. Has the new owner(s), administrator or medical director been affiliated through ownership or employment with any of the facilities listed in rule 3701-83-04(A)(1)(c) of the OAC within five years prior to the date of this application?

No Yes If "yes", provide in writing the individual's name(s) and address(es) of the facilities.

34. Has the owner(s), administrator or medical director been convicted of any criminal conviction, civil judgment or administrative adjudication related to the provision of care or bearing a direct or substantial relationship to the job responsibilities he/she is to carry out?

No Yes If "yes", provide in writing the individual's name, full explanation stating the charge(s), date(s) and disposition(s).

I affirm that to the best of my knowledge and belief, the answers provided herein and all accompanying materials are true and correct. I understand that section 3702.30 of the Ohio Revised Code and paragraph (E) of rule 3701-83-04 of the Ohio Administrative Code require the owner to inform the Director, in writing, of any changes in the information contained in the statement of ownership set forth in the initial application and any change in accreditation status, no later than 30 days after the occurrence of the change.

Any owner named herein may sign the application. That owner's name must appear in question #13 or #26. If the signatory is not an owner, attach a notarized affidavit that the individual is the authorized representative of the owner.

Print/Type owner's/representative's name & title	Signature	Date
David M. Burkens M.D.		11/29/13
Print/Type administrator's name	Signature	Date
Lindsay Marrone		11/20/13
Print/Type medical director's name	Signature	Date
David M. Burkens, M.D.		11/20/13

Ohio Dept Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 1081AS	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 02/03/2014
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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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(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	<p>Initial Comments</p> <p>Initial Licensure Compliance Inspection</p> <p>Administrator: Lindsay Marrone</p> <p>County: Summit</p> <p>Number of ORs: 1</p> <p>The following violations are issued as a result of the initial licensure compliance inspection completed on 02/03/13.</p>	C 000		
C 104	<p>O.A.C. 3701-83-03 (F) Governing Body</p> <p>The HCF shall have an identifiable governing body responsible for the following:</p> <p>(1) The development and implementation of policies and procedures and a mission statement for the orderly development and management of the HCF;</p> <p>(2) The evaluation of the HCF's quality assesment and performance improvement program on an annual basis; and</p> <p>(3) The development and maintenance of a disaster prtpreparedness plan.</p> <p>This Rule is not met as evidenced by: Based on review of governing body minutes and</p>	C 104		

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

Ohio Dept Health

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C 104	<p>Continued From page 1</p> <p>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.</p> <p>Findings include:</p> <p>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.</p>	C 104		
C 123	<p>O.A.C. 3701-83-08 (E) Staff Orientation & Training</p> <p>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.</p> <p>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</p>	C 123		

Ohio Dept Health

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C 123	<p>Continued From page 2</p> <p>who receive surgical procedures from the facility.</p> <p>Findings include:</p> <p>Review of Staff B, C, D, E, and F's personal files completed on 02/03/14 revealed orientation was not completed.</p> <p>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.</p> <p>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.</p>	C 123		
C 151	<p>O.A.C. 3701-83-12 (B) Q A & Improvement Plan</p> <p>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.</p> <p>This Rule is not met as evidenced by: Based on review of policy and procedures and</p>	C 151		

Ohio Dept Health

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C 151	<p>Continued From page 3</p> <p>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.</p> <p>Findings include:</p> <p>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.</p>	C 151		
C 222	<p>O.A.C. 3701-83-18 (C) Director of Nursing</p> <p>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.</p> <p>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.</p> <p>Findings include:</p> <p>Review of the Organizational Flow Chart completed on 02/03/14 revealed no Director of Nursing was listed.</p> <p>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</p>	C 222		

Ohio Dept Health

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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	<p>O.A.C. 3701-83-19 (B) Drug Control & Accountability</p> <p>The ASF shall:</p> <p>(1) Provide adequate space, equipment, and staff for storage and the administration of drugs in compliance with state and federal laws and regulations.</p> <p>(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.</p> <p>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.</p> <p>Findings include:</p> <p>A tour was conducted in the facility with Staff B between 9:50 AM and 10:30 PM. The following medications were observed expired:</p> <p>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.</p>	C 231		

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C 231	<p>Continued From page 5</p> <p>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.</p> <p>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.</p> <p>3. The operating room was observed with a container of lubricant which had expired prior to this date of 02/03/14.</p> <p>These expired medications and supplies were verified with Staff B during tour.</p>	C 231		
C 244	<p>O.A.C. 3701-83-20 (E) Emergency Power</p> <p>Each ASF shall have emergency power available in operative, procedure, and recovery areas.</p> <p>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.</p> <p>Findings include:</p> <p>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</p>	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		

CHECKLIST FOR ASF SURVEYS

FACILITY NE. Ohio Womens Center

PROVIDER # 1081 AS SURVEY DATE 2-3-14 COUNTY Summit

- 1) Green Rod
- 2) Checklist
- 3) Facility Information Document (FID)
- 4) Transfer Agreement (Obtain a Copy for All Survey Types)
- 5) Miscellaneous ODH Documentation/Correspondence



OHIO DEPARTMENT OF HEALTH
 DIVISION OF QUALITY ASSURANCE
 BUREAU OF COMMUNITY HEALTH CARE FACILITIES
 NON LONG TERM CARE QUALITY UNIT

FACILITY INFORMATION DOCUMENT

Facility Name	Northeast Ohio Women's Center	NPI: 1871572289
Address	2127 State Rd.	
City/County	Cuyahoga Falls, OH (Summit)	Zip + 4: 44223
Mailing Address	Same	
City/County	↓	Zip + 4:
E-Mail Address	AA neowc2127@gmail.com	
Administrator Name	Lindsay Marrone	
Other Information	Telephone: (330) 923-4009 Fax: (330) 926-1486	
	Provider No.: N/A Licensure No.: 1081 AS Medicaid No.: N/A	
	Fiscal Intermediary/Carrier: Name/Address/Phone No. N/A	

Facility Type: ASC CAH CORF ESRD HHA HOSPICE PPS PTIP
 REHAB RURAL H X-RAY MLP HOSP HCS

ACCREDITED: Yes No Maternity License Expiration Date: NA
 Fiscal Year: ~~NA~~ 10/31

Action: Certification Licensure PCR/PSR Complaint No. Other
Initial

FACILITY BEDS	TOTAL	HOSPITAL	HOSPICE	PPS PSYCH	PPS REHAB	MATERNAL BEDS	N/B
Total Beds- CR	1						
Total Census	0						

HEALTH SURVEYS

Survey Entry Date: 2/3/14	Entrance Time: 8:30 A.M. P.M.
Day of the Week: (M) T W Th F Sat Sun	
Week of the Month: (1) 2 3 4	
Survey Exit Date: 2/3/14	Exit Time: 4:10 A.M. (P.M.)

LSC SURVEYS

Survey Entrance Date:	Entrance Time: 8:30 4:10 A.M. (P.M.)
Number of Buildings:	Description of Construction Type:
Construction Dates (each bldg):	
Survey Exit Date:	Exit Time: A.M. P.M.

Additional Information On Back

Completed By: Lindsay Marrone	Date: 2/3/14
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TRANSFER AGREEMENT BETWEEN

COPY

Northeast Ohio Women's Center, LLC
and
Summa Akron City and St. Thomas Hospitals

To facilitate continuity of care and timely transfer of patients by appropriate mode of transportation, and to assure transfer of appropriate records and information between Northeast Ohio Women's Center, LLC, 2127 State Rd, Cuyahoga Falls, Ohio 44223 and Summa Akron City and St. Thomas Hospitals located at 525 E. Market St., Akron, Ohio 44304 the parties names above agree as follows:

1. When a patient's need for transfer from one of the above institutions to the other has been determined and substantiated by the patient's physician, the institution to which transfer is to be made agrees to admit the patient as promptly as possible, provided admission requirements in accordance with Federal and State laws and regulations are met and bed space is available to accommodate the patient. Prior to moving the patient, the transferring institution must receive confirmation from the receiving institution that it can accept the patient. Transfer shall be made in accordance with the policies of both the transferring and receiving institution.
2. The transferring institution will provide the receiving institution with as much advance notice possible of a transfer. The transferring institution will send with each patient at the time of transfer, or in the case of emergency, as promptly as possible, the completed transfer and referral forms mutually agreed upon to provide the medical and administrative information necessary to determine the appropriateness of placement and to enable continuing care to the patient. The transfer and referral forms will include such information as current medical findings, diagnosis, a brief summary of the course of treatment followed in the transferring institution, nursing information, ambulation status and pertinent administrative and social information as available.
3. The transferring institution will be responsible for the transfer or the appropriate disposition of personal effects, particularly money and valuables, and information related to these items.
4. The transferring institution shall have the responsibility for obtaining the patient's consent to the transfer to the other institution prior to the transfer, if the patient is competent. If the patient is not competent, the transferring institution shall obtain a family member's consent; if such consent is not possible, the consent of the patient's physician shall be obtained by the transferring institution.
5. The transferring institution will be responsible for effecting the transfer of the patient, including arranging for appropriate and safe transportation using qualified personnel and equipment for the care of the patient during the transfer in accordance with applicable Federal and State law and regulations.

6. Charges for services performed by either institution shall be collected by the institution rendering such services, directly from the patient, third party payer or other sources normally billed by the institution. Neither institution shall be liable to the other for such charges.
7. The Governing Body of each facility shall have exclusive control of policies, management, assets, and affairs of its respective institutions. Neither institution shall assume any liability by virtue of the agreement for any debts or other obligations incurred by the other party to this agreement. Each institution shall be responsible for its own acts and omissions and shall not be responsible for the acts and omissions of the other institution.
8. Each institution shall secure and maintain or cause to be secured and maintained, during the term of this Agreement, comprehensive, general and professional liability insurance, and property damage insurance or shall self insure in an amount adequate to protect such institution in carrying out its duties and responsibilities in accordance with this Agreement. If the other institution so requests, each institution shall provide the other institution with evidence of such insurance coverage.
9. This Agreement shall be interpreted and enforced in accordance with the laws of the State of Ohio.
10. Both institutions are independent contractors. Neither institution is authorized or permitted to act as an agent or employee of the other. Nothing in this Agreement shall in any way alter the freedom enjoyed by either institution, nor shall it in any way alter the control of the management, assets, and affairs of the respective institutions. Neither party, by virtue of this Agreement, assumes any liability for any debts or obligations of either a financial nor a legal nature incurred by the other party to this Agreement.
11. The parties do not intend that individuals receiving services pursuant to this Agreement occupy the position of third party beneficiary to the Agreement.
12. Until the expiration of four (4) years after the furnishing of services pursuant to this Agreement and upon written request of the Secretary of Health and Human Services, or upon written request of the Secretary of Health and Human Services, or upon request of the Comptroller General of the United States, or any other duly authorized representative of the Federal Government, the parties shall make available this Agreement and the books, documents and records of the parties hereto necessary to certify the nature and extent of costs of services rendered, if any, under the terms of this Agreement.
13. Each institution hereby represents and warrants the following:
 - A. that it has not been debarred, excluded, suspended or otherwise determined to be ineligible to participate in federal health care programs (collectively "Debarment" or "Debarred", as applicable); and
 - B. that it shall not knowingly employ or contract with, with or without compensation, any individual or entity (singularly or collectively, "Agent") listed

by a federal agency as Debarred or found on the *List of Specially Designated Nationals and Blocked Persons* maintained by Office of Foreign Assets Control. To comply with this provision, each party shall make reasonable inquiry into the status of any Agent contracted or arranged by it to fulfill the terms of this Agreement by reviewing, at a minimum, the Health and Human Services – Office of Inspector General Excluded Parties List System (<http://epls.gov>), the Health and Human Services Office of Inspector General List of Excluded Individuals/Entities (<http://oig.hhs.gov/fraud/exclusions.asp>), or the List of Specially Designated Nationals and Blocked Persons (<http://www.ustreas.gov/offices/enforcement/ofac/>) which internet sites may be revised from time to time by the U.S. government.

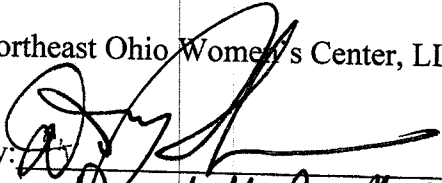
In the event that either party and/or its Agent either (1) becomes Debarred, (2) receives notice of action or threat of action with respect to its Debarment, or (3) is placed on the List of Specially Designated Nationals and Blocked Persons during the term of this Agreement, each party agrees to notify the other immediately. In the event that either party or its Agency becomes Debarred as set forth above, this Agreement relative to such Debarred entity or individual's participation hereunder shall automatically terminate upon receipt of such notice without any further action or notice; and

Each party agrees to act in compliance with all laws and regulations (including, without limitation, Medicare and Medicaid program requirements as applicable) which relate to its performance of this Agreement. Each party agrees to notify the other in a timely manner in the event that it has violated any such statutory or regulatory requirements, and the nature of such violation, to enable non-violating party to take prompt corrective action. Each party agrees that the other shall have the right to automatically terminate this Agreement in the event that the other party fails to comply with this provision.


14. Nothing in this agreement shall be construed as limiting the rights of either institution to contract with any other institution or facility on a limited or general basis.
15. Neither institution party to this agreement shall use the name of the other institution in any promotional or advertising materials without prior consent of the other institution.
16. Both institutions agree to comply with all applicable federal and state laws and regulations.
17. This agreement may be amended by mutual agreement in a writing signed by both parties.
18. This agreement shall be in effect from the date both parties sign. It may be terminated by either institution upon thirty (30) days written notice. The agreement shall be automatically terminated should either institution fail to maintain its licensure or accreditation.

19. This agreement shall be maintained in the institutions' files.

Northeast Ohio Women's Center, LLC

By: 
Name: David M. Burkhas
Title: Owner Medical Director
Date: 1/7/14

Summa Akron City and St.
Thomas Hospitals

By: 
Name: SUSAN SORBORO
Title: Vice President, Women's Health
Date: January 2, 2014

DQA	ADTS
BCHCFS	71511

MEMORANDUM

To: Lance D. Himes, Interim Director

Through: Tim Adams, Chief of Staff

Through: Will McHugh, Assistant Director

Through: Office of General Counsel

From: Rebecca S. Maust, Chief
Division of Quality Assurance

Subject: Northeast Ohio Women's Center - Attorney Requesting Initial
Inspection Report

Date: July 11, 2014

Request for Review of attached documentation asking for status of initial inspection report from 02/03/2014.

FOR USE BY BUREAU STAFF

Prepared by: _____

Section Chief Approval: _____

Bureau Chief Approval: _____

VORYS

106 South Main Street, Suite 1100
Akron, Ohio 44308

Vorys, Sater, Seymour and Pease LLP
Legal Counsel

OHIO DEPT OF HEALTH
DQA-BCHCFS

330.208.1000 | www.vorys.com

Founded 1909

2014 JUL 11 AM 11:45

Stephanie S. Angeloni
Direct Dial (330) 208-1136
Direct Fax (330) 208-1092
Email ssangeloni@vorys.com

July 9, 2014

VIA CERTIFIED

LeaAnn Rose, RN, QMRP, LSC
Health Care Facility Surveyor
Division of Quality Assurance
Bureau of Community Health Care Facilities and Services
Ohio Department of Health
246 N. High Street
Columbus, Ohio 43215

Re: Inspection of Northeast Ohio Women's Center

Dear Ms. Rose:

I am writing to follow up on your initial inspection of Northeast Ohio Women's Center (NEOWC) that took place on February 3, 2014. At this time, NEOWC has not received its initial inspection report. It was NEOWC's understanding that it would receive the inspection report within ten business days of the date of the inspection. It has now been over five months. In an effort to expedite the processing of NEOWC's inspection report, below is a summary of the actions taken by NEOWC to correct the issues identified by you during your inspection:

Suggested Correction	Action Taken
Governing Body meeting, minutes and a written "Quality Assurance" policy in place	Governing Board met on 2/16/2014 and reviewed the Quality Assurance policy already in place. Minutes were taken on all that was discussed by the Board.
The Board must grant Dr. David Burkons privileges to practice at NEOWC.	The Board granted such privileges on 2/16/2014.
All staff needs to be trained (oriented) prior to opening for surgeries at NEOWC.	All staff (regular and on-call) have been trained and oriented on: Key Policies, Safety and Security, Medical Orientation, and Office Orientation. Proof of these trainings can be found in all employee files.

Stephanie S. Angeloni
Direct Dial (330) 208-1136
Direct Fax (330) 208-1092
Email ssangeloni@vorys.com

July 9, 2014

VIA CERTIFIED

Ernest Abercrombie, RN
Health Care Facility Surveyor
Division of Quality Assurance
Bureau of Community Health Care Facilities and Services
Ohio Department of Health
246 N. High Street
Columbus, Ohio 43215

OHIO DEPT OF HEALTH
DOA-BCHCFS
2014 JUL 11 AM 11:45

Re: Inspection of Northeast Ohio Women's Center

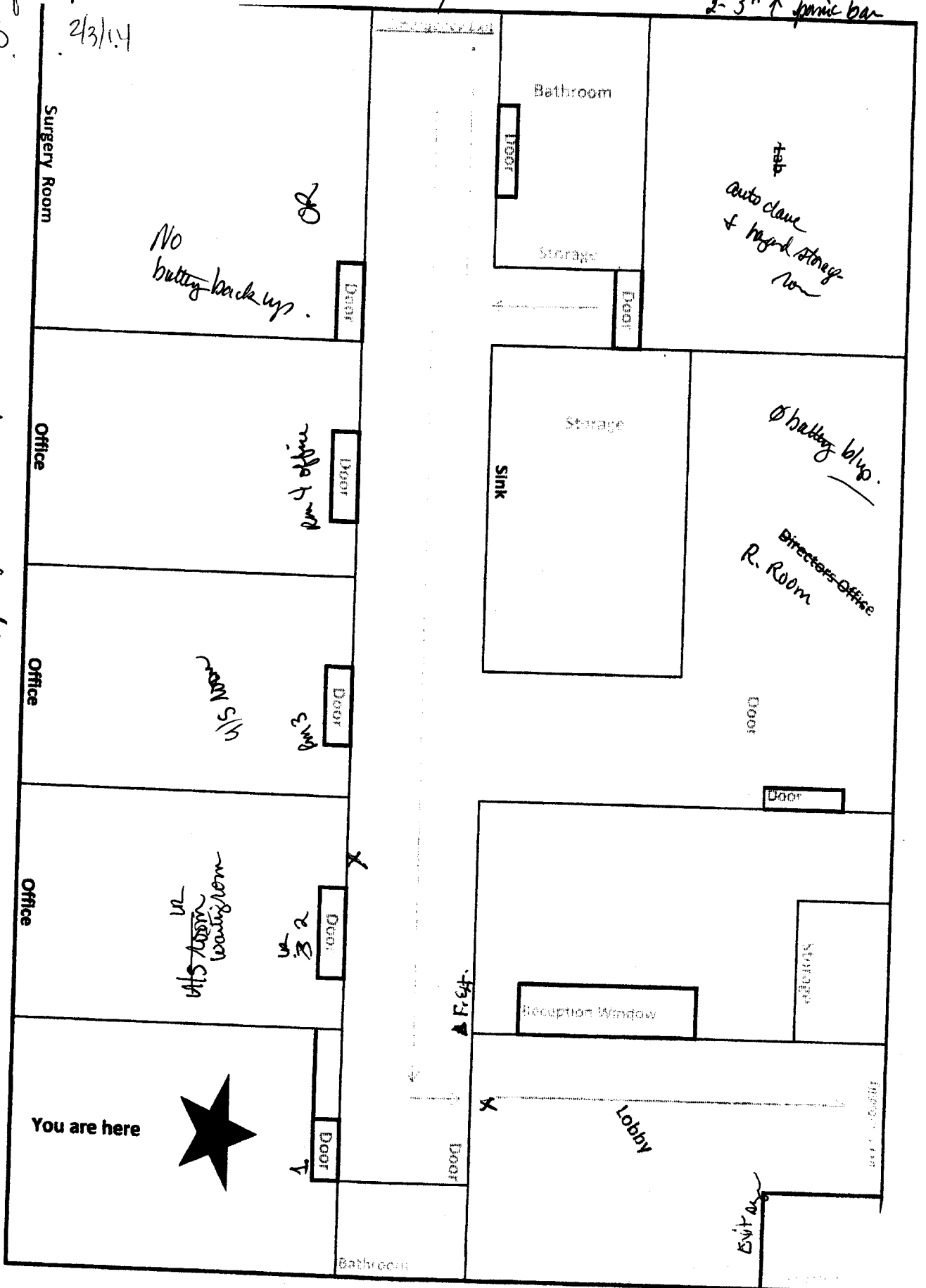
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Updated floor plan ^{done} onsite
1081AS 2/3/14

Exit door - panic hardware & deadbolt on back
2-3" ↑ panic bar



← 48 ft →
Akron Office

← 36 ft →

X = battery blimp light

Stephanie S. Angeloni
Direct Dial (330) 208-1136
Direct Fax (330) 208-1092
Email ssangeloni@vorys.com

July 9, 2014

VIA CERTIFIED

Ernest Abercrombie, RN
Health Care Facility Surveyor
Division of Quality Assurance
Bureau of Community Health Care Facilities and Services
Ohio Department of Health
246 N. High Street
Columbus, Ohio 43215

OHIO DEPT OF HEALTH
DQA-BCHCFS
2014 JUL 11 AM 11:45

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Ernest Abercrombie, RN


July 9, 2014

Page 2

A Director of Nursing needs to be appointed by the Board.	Vicki Smith, RN has been appointed Director of Nursing by the Board as of 2/16/2014.
You stated that flashlights may or may not be sufficient to qualify as emergency lighting and that you would look into such issue.	Flashlights are located in each room of the clinic to be used as emergency lighting. Please inform us if this is sufficient to qualify as emergency lighting.
A vial of Lidocaine was found that had expired the Friday previous to the inspection.	All medications were checked and the expired vial of Lidocaine was discarded on 2/3/2014.
NEOWC needed a policy stating that Dr. Burkons will remain on the premises until all patients have been discharged from the recovery room on surgery days.	A policy stating that Dr. Burkons will remain on the premises until all patients have been discharged from the recovery room on surgery days has been added to NEOWC's Policies and Procedures manual. The policy was approved by Dr. Burkons and the Board on 2/16/14.

Given these corrections, can you give us an expectation of when we will receive the inspection report? It is our understanding that the Ohio Department of Health (ODH) is overburdened with a backlog of both initial inspections and renewal surveys. Please understand that, unlike facilities waiting on renewals, NEOWC cannot operate or receive payment as an ambulatory surgical facility until its initial survey is processed and it is properly licensed. To the extent that ODH is processing renewal reports in advance of NEOWC's initial survey, we kindly request that ODH prioritize NEOWC's initial survey. Please contact me directly at (330) 208-1136 with information regarding NEOWC's inspection report.

Very truly yours,



Stephanie S. Angeloni

SSA/ssa

cc: Wanda Iacovetta ✓
 NLTC Supervisor
 Ohio Department of Health
 246 North High Street, Second Floor
 Columbus, OH 43215