OHIO DEPARTMENT OF HEALTH

246 North High Street
Columbus, Ohio 43215

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

John R. Kasich / Governor

Theodore E. Wymyslo, M.D. / Director of Health

MAR 0 5 2013

T & S Management of Columbus, LLC
Capital Care Network
c/o Terrie Hubbard, R.N.
1243 East Broad Street
Columbus, Ohio 43205

Re: **Notice of Proposal to Revoke License; and**
Notice of Prohibition of Facility from Performing Services
Facility Name: **Capital Care Network**
License Number: **1008AS**

Dear Ms. Hubbard and T & S Management:

You hereby are notified that I propose to issue an order revoking the Health Care Facility license of Capital Care Network located at 2127 State Road, Cuyahoga Falls, Ohio, 44223 (Capital Care), to operate as an ambulatory surgical facility, for violations of section 3702.30 of the Revised Code (R.C.) and Chapter 3701-83 of the Ohio Administrative Code (O.A.C.). This action is taken under authority of section 3702.32 of the R.C., paragraph (C)(2) of O.A.C. rule 3701-83-05.1 and in accordance with Chapter 119. of the R.C.

Additionally, you are hereby notified that I am issuing an order that prohibits Capital Care from performing medical services including surgical procedures, pharmaceutical services, and anesthesia services. This action is taken under authority of section 3702.32 of the R.C., paragraph (C)(3) of O.A.C. rule 3701-83-05.1 and in accordance with Chapter 119. of the R.C. This order is effective at 12:01 a.m. on the first day following the day of receipt of this order.

Representatives of the Ohio Department of Health conducted a licensure compliance inspection at Capital Care, on February 14, 2013. A copy of the report is enclosed and incorporated into this notice by reference. The above listed actions are based on the violations found on the February 14, 2013, inspection.

You are hereby notified that you may request a hearing before me or my duly authorized representative regarding my order to prohibit Capital Care from performing medical, pharmaceutical, and anesthesia services and my proposal to revoke Capital Care's license to operate. Such request must be made in writing and received within thirty days of receipt of this letter and should be directed to the Office of General Counsel, Ohio Department of Health, 246 North High Street, Seventh Floor, Columbus, Ohio, 43215. A request is considered timely if it is received by the Ohio Department of Health via facsimile, 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 appearing 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, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.

Please be advised that if you do not request a hearing within the thirty (30) days allowed, I will issue an adjudication order revoking Capital Care's license to operate. Please call Kathryn Kimmet at (614) 644-6220 if you have any questions about this matter.

Sincerely,

Theodore E. Wymyslo, M.D.
Director of Health

Certified Mail Return Receipt Requested:

7012 3050 0002 1677 2760:	**Capital Care Network**
7012 3050 0002 1677 2753:	**T & S Management of Columbus, LLC**

c: Kathryn Kimmet, Chief, Bureau of Regulatory Compliance
Rachel Belenker, Office of the General Counsel
Tamara Malkoff, Assistant Bureau Chief, Bureau of Information and Operational Support
Capital Care Network

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☒ Agent ☐ Addressee

B. Received by (Printed Name) Vivian Marrow C. Date of Delivery 3-7-13

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

CAPITAL CARE NETWORK
2127 STATE ROAD
CUYAHOGA FALLS, OHIO 44223

☒ Certified Mail ☐ Express Mail
☐ Registered ☒ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

DQA-BRC
DOH301310

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7012 3050 0002 1677 2760

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name) Amarea Martinez C. Date of Delivery 3-6-13

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

T & S MANAGEMENT OF COLUMBUS, LLC
CAPITAL CARE NETWORK
c/o MS. TERRIE HUBBARD, R.N.
1243 EAST BROAD STREET
COLUMBUS, OHIO 43205

COLUMBUS, OHIO 43203-9998 MAR - 2013 USPS

☒ Certified Mail ☐ Express Mail
☐ Registered ☒ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

DQA-BRC
DOH301310

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7012 3050 0002 1677 2753

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

Ohio Dept Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING: B. WING	(X3) DATE SURVEY COMPLETED
	1008AS		02/14/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAPITAL CARE NETWORK	2127 STATE ROAD CUYAHOGA FALLS, OH 44223

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C 000	Initial Comments Type of Inspection; Licensure Compliance Inspection Administrator: Lindsay Marrone County: Summit Number of Operating Rooms: One The following licensure violations were issued as a result of the licensure compliance inspection completed on 02/21/13.	C 000	COPY	
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:	C 104		

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C 104	Continued From page 1 Based on review of facility documentation and facility policy review, the facility failed to ensure an evaluation of the facility's quality assessment and performance improvement program was conducted on an annual basis. The facility provided surgical services for 536 patients within the past 12 months. Findings included: On 02/14/13, a review of the facility's 2012 to present committee meeting minutes was completed. Review of the documentation revealed the minutes were labeled as Director's meetings. The minutes reflected meetings conducted on 08/02/12, 05/24/12, 04/19/12 and 01/23/12. The minutes reflected a discussion of recent inspections, staffing issues and other internal operational items. There was no documentation of an annual report regarding quality assurance activities for the facility. Review of the facility policy regarding quality assurance revealed the clinical directors were to meet every eight weeks. The policy noted that an annual quality assurance report would be reviewed at the meeting.	C 104		
C 119	O.A.C. 3701-83-08 (A) Professional Standards Each HCF shall utilize personnel that have appropriate training and qualifications for the services that they provide. Any staff member who functions in a professional capacity shall meet the standards applicable to that profession, including but not limited to possessing a current Ohio license, registration, or certification, if required by law, and working within his or her scope of practice. Copies of current Ohio licenses, registrations and	C 119		

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C 119	Continued From page 2 certifications shall be kept in the employee's personnel files or the provider of the HCF shall have an established system to verify and document the possession of current Ohio licenses, registrations, or other certifications required by law. Nurse licenses shall be copied in accordance with paragraph (E) of rule 4723-7-07 of the Administrative Code. This Rule is not met as evidenced by: Based on facility observation, medical record review, staff interview and verification, the facility failed to utilize personnel that have appropriate training and qualifications for the services they provide. This deficient practice had the potential to negatively affect any patient who visited the facility. The facility provided surgical services for 536 patients within the last 12 months. Findings included: 1. Review of the personnel file for Staff D revealed that Staff D graduated with a medical assistant degree in 2006. Review of the medical records on 02/21/13, for Patients #36, #37, #38, #39, and #40 revealed that the controlled narcotic medications listed as diazepam (a sedative-hypnotic medication) and hydrocodone bitartate (an opiod based medication for pain) were signed off as administered by Staff D. Review of the facility's 'Controlled Substance Count Sheets' revealed Staff D had signed out narcotic medications for other patients (not reviewed) as well. During an interview on 02/21/13, at 4:35 P.M.,	C 119		

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C 119	Continued From page 3 Staff D verified that the presence of her initials indicated that she had administered the medications to the patients and that she only gave medications when the physician directed her to do so. The rules and regulations regarding the scope of practice of medical assistants are determined based on the Ohio State Medical Board Delegation of Medical tasks code. According to the O.A.C., Chapter 4731-23, delegation of medical tasks, a physician may not delegate, to an unlicensed person, the administration of a controlled substance. 2. During the initial tour conducted the afternoon of 02/13/13, observation of the laboratory room revealed the presence of a locked laboratory refrigerator. Staff D verified the refrigerator contained blood samples used for the performance of laboratory tests and she performed pre-surgical laboratory tests on patients for the Rhesus Factor (Rh Factor). The Rh factor provided the positive or negative portion of the blood type result. When tested and found to be Rh negative, a patient required the administration of the medication Rhogam following surgery to prevent hemolytic disease of the newborn in future pregnancies. On 02/21/13, Staff D was interviewed about the procedure for performance of this test to evaluate staff competency. Staff D verbalized, everyday prior to screening patients for the Rh factor, he/she was required to perform and document an Rh test on both a known positive and a known negative control sample to ensure the efficacy of the reagent used to provide the patients' tests results. Further interview of Staff D on 02/21/13 at 3:12 P.M. revealed the facility does not purchase	C 119		

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C 119	Continued From page 4 commercially prepared Rh positive or negative controls but that their policy and procedure permitted the use of a known positive and a known negative blood sample to be used as a control. When asked how he/she obtained the negative control sample (less than 15% of the United States population is Rh negative), Staff D replied that many of the facility's patients underwent frequent surgical procedures at the facility. Being aware of previous Rh results, Staff D would draw a test tube of blood instead of just a finger prick to obtain a blood sample. This test tube of blood would then be used for controls for the next two weeks. The facility was unable to provide documentation that Staff D was provided a physician's order for the drawing of the test tube of blood used for the control sample nor was there documentation the patient was made aware of the blood sample's intended use.	C 119		
C 120	O.A.C. 3701-83-08 (B) T B Control Plan The HCF shall develop and follow a tuberculosis control plan that is based on the provider's assessment of the facility. The control and assessment shall be consistent with the centers for disease control and prevention (CDC) "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Settings, 2005," MMWR 2005, Volume 54, No. RR-17. The HCF shall retain documentation evidencing compliance with this paragraph and shall furnish such documentation to the director upon request.	C 120		

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C 120	Continued From page 5 This Rule is not met as evidenced by: Based on a review of personnel files, staff interview, and a review of the facility's policy and procedure related to tuberculosis screening, the facility failed to perform either initial tuberculosis (TB) testing or required annual re-testing. This deficient practice had the potential to negatively affect any patient who visited the facility. The facility provided surgical services for 536 patients within the last 12 months. Findings included: Review of personnel files on the afternoon of 02/14/13 revealed Staff Members C, F, G and I had no record of TB testing being performed. The personnel files revealed Staff C had a date of hire of 01/09/12, Staff F had a date of hire of 01/08/13, Staff G had a date of hire of 01/04/06, and staff I had a date of hire of 08/01/12. The most recent annual TB testing for Staff A, D, and E were as follows: Staff A on 10/08/11, Staff D on 12/19/11, and Staff E on 03/10/11. Review of the facility's policy and procedure entitled Centers for Disease Control, Morbidity Mortality Weekly Report (MMWR) dated 12/30/2005, Guidelines for Preventing Transmission of Mycobacterium tuberculosis (TB) in Health-Care Settings directed after baseline testing for infection, healthcare workers should receive TB screening annually. Interview with Staff A on 02/13/13 at 3:00 P.M. verified the facility policy was for all staff to receive annual TB testing.	C 120		

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C 122	Continued From page 6	C 122		
C 122	O.A.C. 3701-83-08 (D) Job Descriptions The HCF shall provide each staff member with a written job description delineating his or her responsibilities. This Rule is not met as evidenced by: Based on a review of the facility's personnel files, staff interview, and a review of the facility's policy and procedure related to the provision of job descriptions, the facility failed to provide written job descriptions to the facility staff. This deficient practice had the potential to negatively affect any patients who received surgical services at the facility. The facility provided surgical services for 536 patients within the last 12 months. Findings included: Review of the employee files with Staff B on 02/13/13 revealed the facility was unable to provide documentation that each employee was provided a written job description. Interview of Staff B revealed the types of staff employed at the facility included registered nurses (RN), licensed practical nurses(LPN), medical assistants, and an administrative director. The records revealed staff were hired between 01/14/06 and as recently as 01/13/13. Review of the policy and procedure entitled "Personnel and Staffing" with a most recent review date of 12/12/12 directed that each staff member shall be provided with a written job description upon hire. Review of the "New Employee Checklist and Orientation" form at	C 122		

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C 122	Continued From page 7 item 11 revealed a space where the employee was to initial receipt of a job description, as well as a place to sign a Receipt of Job Description form. Each item on the checklist space for both the employee and the facility staff was filled in for compliance. Interviews completed on 02/21/13 at 2:40 P.M. with Staff C, at 3:05 P.M. with Staff F and with Staff B on 02/13/13 at 3:05 P.M. revealed the facility was unable to provide documentation that all staff had been provided written job descriptions.	C 122		
C 125	O.A.C. 3701-83-08 (G) Staff Performance Evaluation Each HCF shall evaluate the performance of each staff member at least every twelve months. This Rule is not met as evidenced by: Based on a review of personnel files, a review of the facility's policy and procedures, and staff interview and verification, the facility failed to provide annual evaluations for their staff. This deficient practice had the potential to negatively affect any patients who received surgical services at the facility. The facility provided surgical services for 536 patients within the last 12 months. Findings included: Review of seven facility staff personnel files (Staff A, C, D, E ,F ,G, and H) was conducted with Staff B on the afternoon of 02/13/13. Review of the personnel files revealed the facility was unable to	C 125		

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C 125	Continued From page 8 provide documentation that annual evaluations for five (Staff A, C, D, E, and G) of the seven employee,s who had been employed greater than one year, was completed. Review of the policy and procedure entitled "Personnel and Staffing", directed that each staff member would be evaluated at least every 12 months. Interview with Staff B on 02/14/13 at 4:00 P.M. verified the facility failed to perform annual evaluations on five staff who were employed greater than 12 months.	C 125		
C 126	O.A.C. 3701-83-08 (H) Staff Schedules Each HCF shall retain staffing schedules, time-worked schedules, on-call schedules, and payroll records for at least two years. This Rule is not met as evidenced by: Based on a review of facility documentation, a review of the facility's policy and procedure, and staff interview, the facility failed to maintain comprehensive and staff specific facility work schedules. This deficient practice had the potential to negatively affect any patients who received surgical services at the facility. The facility provided surgical services for 536 patients within the last 12 months. Findings included: Review of the facility's staff work schedules for the past 12 months revealed the facility was unable to provide staff work schedules for the	C 126		

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C 126	Continued From page 9 months of July, October, and November 2012 when this information was requested. Additionally, review of the remaining schedules failed to consistently identify all staff scheduled to work on any particular day. The master schedule consisted of a photocopy of the current month's calendar. The individual days were marked with the days the physician saw patients for either a consult or surgery by placing the physician's initials on the day patients were to be seen by the physician. An 'Sx' in addition to the physician's initials indicated that surgeries were scheduled on that day. The individual days contained initials of only facility administrative and ancillary staff, but rarely contained the initials or names of any nursing staff. When the facility was requested to provide the time cards for the months of December 2012 and January 2013 to determine which nursing staff worked and when, Staff C provided only three time cards for December 2012. One time card for Staff I, was hand written and documented that Staff I worked from 8:30 A.M. until 1:00 P.M. on some unknown day in December 2012. A time card for Staff H indicated time worked was from 8:30 A. M. until 1:00 P.M. on 12/27/12. Review of the corresponding medical records obtained from the surgery schedule indicated surgeries were performed on 12/27/13. The master calendar schedule did not indicate 12/27/12 was a surgery day. Review of the time cards for the month of January 2013 indicated Staff I worked on a Tuesday in January 2013. Review of the master calendar schedule indicated there were five	C 126		

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C 126	Continued From page 10 Tuesdays in January 2013. The time card for Staff F indicated they worked on two of the five Tuesdays in January, but it could not be determined which Tuesday was worked without reviewing individual medical records of patients seen on a Tuesday. Review of the facility's policy entitled "Personnel and Staffing", directed the facility to maintain staff schedules, time worked schedules, on call schedules and payroll records for at least two years. Interview with Staff C on 02/14/13 at 12:10 P.M. revealed that either Staff A or C made the monthly schedules and that the schedule failed to consistently reflect nursing staff on the schedule. Staff C further stated there was no easy way to determine which nurses worked on which days without reviewing individual patient records to see which nursing staff signed the medical records.	C 126		
C 129	O.A.C. 3701-83-09 (A) Standards of Practice The HCF shall assure all staff members provide services in accordance with: (1) Applicable current and accepted standards of practice and the clinical capabilities of the HCF; and (2) Applicable state and federal laws and regulations. This Rule is not met as evidenced by: Based on record review and staff interview, the facility failed to ensure that all staff members	C 129		

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C 129	Continued From page 11 provided services in accordance with applicable current and accepted standards of practice. The facility provided surgical services for 536 patients within the last 12 months. Findings included: During a tour of the facility, locked medication storage areas were noted. During an interview on 02/13/13, Staff A revealed the facility maintained an account of the controlled medications. On 02/14/13, a review of the controlled medication account sheets for Schedule II controlled medications was conducted. Review of the medication records revealed the facility count included the amount of Fentanyl 125 micrograms per 25 millimeters and Versed 5 milligram per milliliter on surgical days. Both medication sheets began on 01/08/13 with the last count being completed on 02/13/13. Review of the schedule II medication count records revealed the amounts were to be initialed and witnessed. Review of the Versed record sheet revealed 10 occasions when the count was not witnessed by another person. Review of the Fentanyl record revealed seven occasions when the count was not witnessed by another person. Review of the facility's policy regarding Schedule II medication counts revealed that the count of the medications was to be completed by the registered nurse and witnessed by the managing physician.	C 129		
C 130	O.A.C. 3701-83-09 (B) Ancillary & Support Services The HCF shall have the ancillary and support services necessary for the provision of the HCF's	C 130		

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C 130	Continued From page 12 services. This Rule is not met as evidenced by: Based on facility observation and staff interview and verification, the facility failed to ensure ancillary support services, specifically pharmacy services, was available for the provision of services. The facility provided surgical services for 536 patients in the past 12 months. Findings included: A review of the facility documentation on 02/13/13 and 02/14/13 revealed the Ohio State Board of Pharmacy license had expired on December 31, 2012. Review of medical records and interview with Staff A on 02/13/13 verified that the facility continued to provide surgical procedures with medication administration without an active pharmacy license since January 1, 2013. On 02/13/13 Staff A verified the facility had been in contact with the Ohio Board of Pharmacy regarding a different address noted on the current pharmacy license. Staff A further stated that no additional action had occurred regarding the pharmacy license. On 02/14/13 at 4:00 P.M. the facility provided an email from the Ohio Board of Pharmacy that indicated the information needed to renew the license had been received from the facility, but the license had not been activated.	C 130		
C 139	O.A.C. 3701-83-10 (B) Safety & Sanitation The HCF shall be maintained in a safe and sanitary manner.	C 139		

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C 139	Continued From page 13 This Rule is not met as evidenced by: Based on facility observation and staff interview and verification, the facility failed to maintain a safe and sanitary environment. Potentially any patient, visitor or staff in the facility could be affected. The facility provided surgical services for 536 patients within the past 12 months. Findings included: 1. On 02/13/13 at 12:45 P.M., a tour of the facility was conducted with Staff A and C. The tour revealed there were two means of entrance/exit for the building. The front entrance lead patients to the waiting area from the parking lot at the front of the building. The back door of the facility allowed for entrance from a back parking lot. The back entrance lead to a corridor outside the operating room and the recovery area. Staff present on tour stated the back door was used for patients at discharge. Observation of the door leading out of the building revealed the solid door had a deadbolt in place. If locked, the deadbolt required turning of a thumb turn to release the bolt and turning a door knob in order to open the door. Staff further verified the door usually remained locked because they did not want patients and visitors entering the building near the operating room and recovery areas. Staff verified that in case of an emergency the door required two actions in order to open the door. 2. During a tour of the facility, Staff A was interviewed regarding the cleaning procedures for	C 139		

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C 139	Continued From page 14 the patient care areas. Staff A indicated there was no contracted cleaning company for the facility and that staff do the cleaning. Further interview regarding cleaning of hard surfaces such as the operating room table, counter tops,and recovery room recliners revealed a disinfectant mixture was to be used. Staff A produced a spray bottle in which the disinfectant mixture was prepared. The spray bottle contained very little mixture. Staff A indicated that, when prepared, the bottle was to be dated. Observation of the spray bottle revealed a date of 12/27/2011. Staff A verified it was not known how long ago the mixture had been prepared and that staff had not been dating the prepared disinfectant as required.	C 139		
C 143	O.A.C. 3701-83-11 (A) Medical Records The HCF shall maintain a medical record for each patient that documents, in a timely manner and in accordance with acceptable standards of practice, the patient's needs and assessments, and services rendered. Each medical record shall be legible and readily accessible to staff for use in the ordinary course of treatment. This Rule is not met as evidenced by: Based on medical record review and staff interview and verification, the facility failed to maintain a medical record for each patient that documented, in a timely manner and in accordance with acceptable standards of practice, the patient's needs and assessments, and services rendered. Six of 19 patient medical records were affected. The facility provided	C 143		

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C 143	Continued From page 15 surgical services for 536 patients within the past 12 months. Findings included: Review of patient medical records on 02/13/13 revealed the following: Patient #6 was admitted to the facility on 12/05/12. Review of the surgical procedure documentation revealed there was no documented evidence the identification of the patient was checked, a physical exam was completed, or that a beginning or ending time for the procedure had been recorded. Review of the checklist before anesthesia revealed no vital signs were checked before or after the IV sedation. Review of patient medical records on 02/21/13 revealed the following: Patients #33, #36, #37, #39 and #43 were admitted between 10/29/12 and 02/14/13. The medical records were noted to be either illegible and undecipherable in regards to the surgical procedures performed by the physicians. The physicians' post operative orders were illegible and surgical procedures lacked beginning and ending times These findings were verified during interview with Staff C on 02/21/13 at 4:40 P.M.	C 143		
C 152	O.A.C. 3701-83-12 (C) Q A & Improvement Requirements The quality assessment and performance improvement program shall do all of the following:	C 152		

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C 152	Continued From page 16 (1) Monitor and evaluate all aspects of care including effectiveness, appropriateness, accessibility, continuity, efficiency, patient outcome, and patient satisfaction; (2) Establish expectations, develop plans, and implement procedures to assess and improve the quality of care and resolve identified problems; (3) Establish expectations, develop plans, and implement procedures to assess and improve the health care facility's governance, management, clinical and support processes; (4) Establish information systems and appropriate data management processes to facilitate the collection, management, and analysis of data needed for quality assessment and performance improvement, and to comply with the applicable data collection requirements of Chapter 3701-83 of the Administrative Code; (5) Document and report the status of quality assessment and improvement program to the governing body every twelve months; (6) Document and review all unexpected complications and adverse events, whether serious injury or death, that arise during an operation or procedure; and (7) Hold regular meetings, chaired by the medical director of the HCF or designee, as necessary, but at least within sixty days after a serious injury or death, to review all deaths and serious injuries and report findings. Any pattern that might indicate a problem shall be investigated and remedied, if necessary.	C 152		

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C 152	Continued From page 17 This Rule is not met as evidenced by: Based on staff interview and verification, the facility failed to ensure that the quality assessment and performance improvement program functioned in accordance to this rule. The facility provided surgical services for 536 patients within the past 12 months. Findings included: Upon entrance on 02/13/13 the facility was requested to provide information related to the quality assurance (QA) program. The information was to include identification of members of the quality assurance program, projects of the QA committee, and meeting minutes. Review of the facility's QA policy was completed. The policy indicated the clinical directors were to meet every eight weeks. On 02/14/13, review of the facility's committee meeting minutes conducted in 2012 and to date in 2013 was completed. The minutes reflected meetings were conducted on 08/02/12, 05/24/12, 04/19/12 and 01/23/12. The minutes reflected discussion of recent inspections, staffing issues and other internal operational items. There was no indication of a discussion of QA projects or actions for specific QA projects already in place. None of the meeting minutes reflected that the committee had reviewed the status of the quality assessment and improvement program and issued a report to the governing body as directed by this rule. On 02/21/13, at 5:00 P.M. Staff C verified there was no QA information available for review that	C 152		

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C 152	Continued From page 18 reflected the QA activities of the facility.	C 152		
C 201	O.A.C. 3701-83-16 (B) Governing Body Duties The governing body shall: (1) At least every twenty-four months review, update, and approve the surgical procedures that may be performed at the facility and maintain an up-to-date listing of these procedures; (2) Grant or deny clinical (medical-surgical and anesthesia) privileges, in writing and reviewed or re-approved at least every twenty-four months, to physicians and other appropriately licensed or certified health care professionals based on documented professional peer advice and on recommendations from appropriate professional staff. These actions shall be consistent with applicable law and based on documented evidence of the following: (a) Current licensure and certification, if applicable; (b) Relevant education, training, and experience; and (c) Competence in performance of the procedures for which privileges are requested, as indicated in part by relevant findings of quality assessment and improvement activities and other reasonable indicators of current competency. (3) In the case of an ASF owned and operated by a single individual, provide for an external peer review by an unrelated person not otherwise affiliated or associated with the individual. The external peer review shall consist of a quarterly audit of a random sample of surgical cases.	C 201		

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C 201	Continued From page 19 This Rule is not met as evidenced by: Based on review of the facility's surgical schedules and staff interview, the facility failed to provide personnel files and physician credentialing documentation for one (Staff K) of three physicians reviewed for current credentialing status. This deficient practice had the potential to negatively affect 17 patients treated by Staff K. The facility provided surgical services for 536 patients within the last 12 months. Findings included: Review of the facility's surgical schedule for the month of August 2012 revealed Staff K was scheduled. Staff K performed surgical procedures on 08/15/12 for eight patients and provided medical consultations for an additional nine patients. On 02/21/13 at 3:32 P.M., Staff C was asked to provide the personnel and credentialing file for Staff K. Staff C verbalized that Staff K had only performed surgical procedures on one day in the fall when another staff member had a family emergency. Staff C verbalized Staff K was an independent contractor and there would be little in the way of personnel records and credentialing available. On 02/21/13 at 5:05 P.M., a second request was made to Staff C for the personnel and credentialing file for Staff K. Staff C verbalized some documentation was emailed from the	C 201		

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C 201	Continued From page 20 human resources department located in another part of the state but Staff C was unable to print it. A request was made to send the requested information via email. As of 02/22/13 no email containing the requested documentation had been received.	C 201		
C 214	O.A.C. 3701-83-17 (I) Patient Accompanied at Discharge The ASF shall discharge a patient only if accompanied by a responsible person, unless the attending or discharging physician, podiatrist, or anesthesia qualified dentist determines that the patient doesnot need to be accompanied and documents the circumstances of discharge in the patient's medical record. This Rule is not met as evidenced by: Based on medical record review and staff interview and verification, the facility failed to discharge a patient only if accompanied by a responsible person, unless the attending or discharging physician, determined that the patient did not need to be accompanied and documented the circumstances of discharge in the patient's medical record. Two patient medical records (Patents #1 and #2) were affected. The facility provided surgical services for 536 patients within the last 12 months. Findings included. On 02/13/13, the medical records for Patients #1 and #2 were reviewed. Patient #1 was admitted to the facility for a procedure on 10/16/12. Admission information in	C 214		

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C 214	Continued From page 21 the medical record was to identify the person who was to transport the patient home after the procedure. In addition, the information was to include the telephone or cellular number where the person could be reached or if the person was waiting on the patient at the facility. This information area was left blank with no person identified as to who would transport the patient home after the procedure. Further review of the medical record revealed Patient #1 received intravenous medication for sedation at 1:00 P.M. The patient was discharged at 1:40 P.M. with no documented evidence that another person transported the patient home. Review of the medical record for Patient #2 revealed the patient was admitted to the facility for a surgical procedure on 09/04/12. Review of the admission information in the medical record regarding the person who was to transport the patient home revealed the information to be left blank. The medical record contained no documented evidence the patient was accompanied by another person upon discharge. The medical record further revealed that Patient #2 received intravenous medication for sedation at 9:20 A.M. At 9:54 A.M. the patient was discharged from the facility with no documented evidence that another person transported the patient home. During an interview of Staff A on 02/13/13, Staff A verified that both patients were to have transportation by other persons due to the medication given. Staff A verified the medical records did not contain documented evidence that both patients were discharged with an escort.	C 214		

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C 225	O.A.C. 3701-83-18 (F) Nurse Duty Requirements At all times when patients are receiving treatment or recovering from treatment until they are discharged, the ASF shall meet the following requirements: (1) At least two nurses shall be present and on duty in the ASF, at least one of whom shall be an RN and at least one of whom is currently certified in advanced cardiac life support and who shall be present and on duty in the recovery room when patients are present; (2) In addition to the requirement of paragraph (F) (1) of this rule, at leastone RN shall be readily available on an on-call basis; and (3) Sufficient and qualified additional staff to attend to the needs of the patients shall be present. This Rule is not met as evidenced by: Based on medical record review and staff interview, the facility failed to assign an Advanced Cardiac Life Support (ACLS) certified registered nurse (RN) to the post surgical recovery room. This affected ten of 19 patients (Patients #33, #37,#38, #39, #40, #41, #42, #43, #45 and #46) whose medical records were reviewed. Potentially any patient who received surgical services could be affected. The facility provided surgical services for 536 patients within the last 12 months. Findings included:	C 225		

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C 225	Continued From page 23 Review of the medical records for Patients #33, #37, #38, #39, #40, #41, #42, #43, #45 and #46, whose admission dates to the facility were between 10/2012 to 02/13/13, revealed the portion of the surgical procedure flow sheet dedicated to the recovery room documentation was consistently initialed as being performed by Staff E. Review of the personnel file for Staff E revealed he/she was a licensed practical nurse (LPN) and did not have ACLS certification. Review of an untitled and undated facility directive revealed, "if a recovery room is being covered by an RN only 1 signature is needed. Need an RN signature along with the LPN signature if the LPN is covering the recovery room." Interview with Staff F on 02/21/13 at 2:35 P.M. revealed that registered nurses (RN) were always assigned to the surgery room should intravenous medications need to be administered. The RNs were responsible for performance of this task. Staff F further verbalized when he/she was assigned to work with Staff E, Staff E was always assigned and worked in the recovery room, as the RNs were needed in surgery. Interview with Staff C on 02/21/13 at 3:30 P.M. revealed that he/she and Staff A were responsible for making the schedule. Staff C verified Staff E was always assigned to the recovery room as RNs were needed in the surgical procedure room.	C 225		
C 227	O.A.C. 3701-83-18 (H) Ongoing Training for Staff Each ASF shall provide an ongoing training program for its personnel. The program shall provide both orientation and continuing training to all staff members. The orientation shall be	C 227		

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C 227	Continued From page 24 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 a review of personnel files of facility staff, a review of the facility's policy and procedure, and staff interview and verification, the facility failed to provide documentation that staff had participated in ongoing training programs and completed the annual infection control training. This deficient practice had the potential to negatively affect any patients who received surgical services at the facility. The facility provided surgical services for 536 patients within the last 12 months. Findings included: Review of the employee files with Staff B on the afternoon of 02/13/13 revealed the facility was unable to provide documentation that all staff had participated in on-going training that included the annual Occupational Safety and Health Administration (OSHA) infection control training. Review of the facility's policy and procedure entitled Personnel and Staffing, revealed that on-going training for job duties would be provided. Six of seven personnel files reviewed had no documented evidence the OSHA infection control training had been completed.	C 227		

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C 227	Continued From page 25 Interview with Staff B on 02/13/13 revealed that staff are supposed to access the OSHA computerized infection control training, complete the module, and answer a post-training test, then generate their own certificates. Staff B verbalized this was to be completed annually. In addition, Staff B could not provide documentation the facility staff had participated in any on-going job related training over the past 12 months. These findings were verified at the time of the interview.	C 227		
C 228	O.A.C. 3701-83-18 (I) Obtaining Informed Consent Each ASF shall require that each physician who practices at the facility complies with any provision of the Revised Code related to the obtaining of informed consent from a patient. This Rule is not met as evidenced by: Based on medical record review and staff interview and verification, the facility failed to require that each physician who practiced at the facility complied with any provision of the Revised Code related to obtaining informed consent from a patient. One of 19 patient medical records (Patient #33) was affected. The facility provided surgical services to 536 patients in the past 12 months. Findings included: Review of the medical record for Patient #33 revealed the patient was admitted to the facility on 01/02/13 for a pre-surgery consultation. This consultation included the performance of a required ultrasound diagnostic test. The	C 228		

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C 228	Continued From page 26 ultrasound report form contained two signature lines, one for the staff performing the test and one for the patient acknowledging that the patient had been offered an opportunity to view the ultrasound image. The form also noted the patient had been offered a physical picture of the ultrasound. Review of the form in the medical record for Patient #33 revealed the ultrasound report contained the initials of the staff who completed the diagnostic test. The two lines for patient acknowledgement were left blank. Interview with Staff A on 02/14/13 at 2:40 P.M. verified there was no way to determine if the facility was in compliance with the requirement for provision of the ultrasonic image to the patient prior to surgery as the patient did not sign the form.	C 228		
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 facility observation, review of facility	C 231		

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C 231	Continued From page 27 documentation, and staff interview and verification, the facility failed to ensure storage and the administration of drugs was in compliance with state and federal laws and regulations. In addition, the facility failed to implement a program for the control and accountability of drug products throughout the facility. The facility provided surgical services for 536 patients within the past 12 months. Findings included: A review of the facility's documentation on 02/13/13 and 02/14/13 revealed the Ohio State Board of Pharmacy license and the Drug Enforcement Administration (DEA) Controlled Substance Registration Certificate were expired. The Ohio State Board of Pharmacy license expired December 31, 2012 and the DEA controlled Substance Certificate expired December 31, 2011. On 02/13/13 and 02/14/13, during a tour of the facility, the presence of locked medication storage areas were noted. During an interview on 02/13/13, Staff A stated that the facility maintained an account of the controlled medications. On 02/14/13, a review of the controlled medication account sheets for Schedule II controlled medications was conducted. Review of the medication records revealed the facility count included the amount of Fentanyl 125 micrograms per 25 millimeters and Versed 5 milligram per milliliter on surgical days. Both medication sheets began on 01/08/13 with the last count being completed on 02/13/13. The Fentanyl medication record indicated there was no drug in the facility. Observation inside the medication box verified there was no Fentanyl in the medication box.	C 231		

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C 231	Continued From page 28 Review of the Schedule II medication count records revealed the amounts were to be initialed by the person who counted the medication and witnessed. Review of the Versed record sheet revealed there was 10 occasions when the accounting was not witnessed by another person. Review of the Fentanyl record revealed there was seven occasions when the count was not witnessed by another person. Review of the facility's policy regarding Schedule II medication counts revealed that the count of the medications was to be completed by the registered nurse and witnessed by the managing physician. One locked medication storage area was a small box like container, which sat on top of a file cabinet in an administration office. The office was used by the facility administrator, owner, and physicians. The box like container was equipped with a double lock but was not secured to the file cabinet or any other structure. The medication storage box could easily be picked up and carried out. On 02/13/13, an observation was noted of a small portable box located in the operating room on a counter top. The small box was unlocked and contained emergency medications that included 10 vials epinephrine, four vials of a diuretic, and 50 milliliters of lidocaine. On 02/21/13, at 2:25 P.M., Drug Enforcement Administration (DEA) staff arrived at the facility to conduct a review for the pending application. After conducting interviews with facility Staff C, D, and J, the DEA staff conducted a review of the controlled substances kept by the facility.	C 231		

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C 231	Continued From page 29 Observation inside the medication box kept on the file cabinet revealed the presence of six syringes containing Fentanyl. The syringes of Fentanyl had a label attached with the initials "TH" and a date of 02/13/13. The medication record for the Fentanyl reflected zero medication in the facility. DEA staff verified the medication record and noted the inconsistent notation. After an interview of Staff C, Staff D, and Staff J and observation of the stored controlled substances, the controlled substances were removed from the facility by DEA staff. Interview of DEA staff verified the agency failed to remain in compliance with 21 C.F.R. 1301.11(a), 21 C.F.R.1301.12 (a) and 21 C.F.R. 1301.13 (a) which addressed the registration requirements for a DEA controlled substance certificate by a facility.	C 231		
C 234	O.A.C. 3701-83-19 (E) Transfer Agreement The ASF shall have a written transfer agreement with a hospital for transfer of patients in the event of medical complications, emergency situations, and for other needs as they arise. A formal agreement is not required in those instances where the licensed ASF is a provider-based entity of a hospital and the ASF policies and procedures to accommodate medical complications, emergency situations, and for other needs as they arise are in place and approved by the governing body of the parent hospital.	C 234		

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C 234	Continued From page 30 This Rule is not met as evidenced by: Based on a review of the facility's transfer agreement and interview with the facility staff, the facility failed to ensure that a current written transfer agreement was in place with a hospital for transfer of patients in the event of medical complications, emergency situations, or for other needs as they arise. This had the potential to affect all patients cared for at the facility. The facility provided surgical services for 536 patients within the past 12 months. Findings included: The facility's transfer agreement between the facility and a local hospital was reviewed on 02/13/13. Review of the agreement, in effect since December 2011, revealed that continuity of care and timely transfer of patients was limited to trauma patients. Interview of Staff B on the afternoon of 02/13/13 verified the transfer agreement needed to be revised to accurately reflect the transfer of patients in the event of medical complications, emergency situations, or for other needs as they arise.	C 234		
C 235	O.A.C. 3701-83-19 (F) Documented Informed Consent Prior to the surgery, the physician, podiatrist, or dentist, shall obtain a statement documenting informed consent, signed by the patient or patient representative, for the performance of the specific surgical procedure or procedures. This statement shall be made part of the patient's medical record. The ASF shall ensure that informed consents for surgical	C 235		

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C 235	Continued From page 31 procedures have been signed. This Rule is not met as evidenced by: Based on medical record review and staff interview, the facility failed to obtain informed consent for an invasive medical procedure for one of 19 patients (Patient #30) whose medical record was reviewed. This deficient practice had the potential to negatively affect any patient who visited the facility. The facility provided surgical services for 536 patients within the last 12 months. Findings included: Review of the medical record for Patient #30 revealed the patient was admitted to the facility on 12/04/12 for a pre-surgery procedure. Review of the 'Consent Form for Laminaria/Lamicel Insertion" (device used to dilate the cervix) indicated the form contained a description of the procedure, the risks and benefits, as well as possible side effects of the insertion of this device. The informed consent contained a signature line for the patient, as well as the staff witnessing the patient's signature prior to the initiation of this procedure. The line Patient #30 was to sign was observed to be blank and the staff witnessing the patient's signature line bore the signature of facility Staff D. Interview with Staff A on 02/13/13 at 10:30 A.M. verified an invasive medical procedure was performed prior to the written consent of the patient.	C 235		

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C 241	Continued From page 32	C 241		
C 241	O.A.C. 3701-83-20 (B) OR & Recovery Room Equipment Each ASF shall have the following equipment accessible to the operating suite and recovery area: (1) Adequate resuscitation equipment: (a) ASFs providing surgical procedures under topical and local infiltration blocks with or without oral or intramuscular preoperative sedation shall have: airways, bag mask respirator, oxygen source, suction equipment, and age-appropriate resuscitative drugs; (b) ASFs providing surgical procedures performed in conjunction with oral, parenteral, or intravenous sedation or under analgesic or dissociative drugs or providing surgical procedures that require general or regional block anesthesia and support of vital bodily functions shall have: airways, endotracheal tubes, laryngoscope, oxygen delivery capability under positive pressure, suction equipment, and suitable resuscitative drugs. (2) Appropriate monitoring equipment: (a) Each ASF shall have size-specific blood pressure apparatus and stethoscopes, electrocardiogram, oscilloscopes and when pediatric patients are treated, size-specific emergency equipment and medications; (b) ASFs performing surgical procedures in conjunction with oral, parenteral, or intravenous sedation or under ananalgesic[sic] or dissociative drugs, or performing surgical procedures that require general or regional block anesthesia and support of vital bodily functions shall have a defibrillator, pulse oximeter with alarm, and temperature monitor. (c) ASFs using inhalation anesthesia shall have an anesthesia machine.	C 241		

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C 241	Continued From page 33 (3) Each ASF shall have suitable surgical instruments customarily available for the planned surgical procedure in the operating suite. (4) Each ASF shall have in the recovery room, an emergency call system that is connected electronically, electrically by radio transmission or in a like manner and that effectively alerts staff. This Rule is not met as evidenced by: Based on facility observation and staff interview and verification, the facility failed to have a laryngoscope accessible to the operating suite and recovery area. The facility provided surgical services for 536 patients within the past 12 months. Findings included: On 02/13/13 at 12:45 P.M., a tour of the facility was conducted with Staff A and C. Observation of the operating and recovery room areas revealed there to be no laryngoscope in the rooms. On 02/14/14 during observation with Staff J of all locked cabinets in the operating room, Staff J verified there was no known laryngoscope in the rooms.	C 241		