South Dakota Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	41051 S	A. BUILDING: _____ B. WING _____	08/20/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
OPHTHALMOLOGY LTD EYE SURGERY CENTER LLC	6601 S MINNESOTA AVE SUITE 100 SIOUX FALLS, SD 57108

(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
S 000	Compliance/Noncompliance A recertification health survey for compliance with 42 CFR Part 416, Subpart C, requirements for Ambulatory Surgery Centers was conducted from 8/19/24 through 8/20/24. Ophthalmology Ltd, Eye Surgery Center LLC was found not in compliance with the following requirement: S097.	S 000	Our current health assessment forms will be evaluated and signed off by a licensed health professional within 14 days of hire. All existing employee health assessment forms will be reevaluated and signed off of by a licensed health care professional. The clinical director will pull all existing files and audit for 100% compliance. The clinical director will then do an audit for a total of 6 months on all new hires as they are brought into employment at our facility. The results of this audit will be reported to the QA Committee and the Governing Body Board at the next scheduled meeting. 09/11/2024 Addendum: The new health assessment form will include a statement that clearly identifies whether or not the employee is free from communicable disease and signed off by a licensed health care professional. Our current health assessment form in current employee files will be reevaluated with an added updated statement clearly identifying the employee as free from communicable disease and signed off by a licensed health care professional. The audit the clinical director will do of the existing employee files will be reported to the QA committee at the 3rd Quarter meeting scheduled on Oct 16, 2024.	10/1/2024
S 097	44:76:04:07 Employee Health Program The facility shall have an employee health program for the protection of the patients. All personnel shall be evaluated by a licensed health professional for freedom from reportable communicable disease which poses a threat to others before assignment to duties or within 14 days after employment including an assessment of previous vaccinations and a tuberculin skin tests or blood assay test. The facility may not allow anyone with a communicable disease, during the period of communicability, to work in a capacity that would allow spread of the disease. Any personnel absent from duty because of a reportable communicable disease which may endanger the health of patients and fellow employees may not return to duty until they are determined by a physician, physician ' s designee, physician assistant, nurse practitioner, or clinical nurse specialist to no longer have the disease in a communicable stage. This Administrative Rule of South Dakota is not met as evidenced by: Based on interview, employee file review, and policy review, the provider failed to ensure three of three sampled employees (E, F, and G) were evaluated for reportable communicable disease by a licensed health professional prior to assignment of duties or within 14 days of hire. Findings include:	S 097		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: *Lindsey Beckstrand* — TITLE: Clinical Director — (X6) DATE: 09/112024

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S 097	Continued From page 1 1. Review of employees E, F, and G's New Employee Health Assessment forms revealed: *Employee E was hired on 7/24/24 and signed her form on 8/12/24. *Employee F was hired on 7/24/23 and signed her form on 7/24/23. *Employee G was hired on 7/15/24 and signed her form on 7/15/24. Interview on 8/20/24 at 1:47 p.m. with clinical director D and registered nurse (RN), Infection Prevention/Employee Health C confirmed: *Each of the above listed employees had signed their own health assessment form. *Those employee health assessment forms were not evaluated for communicable diseases or signed as completed by a licensed health professional. *They were not aware a licensed health professional should have completed the health assessment evaluations. Review of the provider's March 2018 Notification of Communicable Diseases to Health Authorities policy revealed: *A licensed health professional should have evaluated employees upon hire or within 14 days of employment had not been addressed. *The purpose of the policy identified the notification process for local, state, and federal public health departments when a patient or employee had been diagnosed or suspected to have a reportable communicable disease.	S 097	These results will also be reported to the Governing Body Board, by the Clinical Director at their next scheduled meeting to be held on September 30, 2024. The results of the 6 month audit will be reported monthly to the QA Committee by the Clinical Director. These results will also be reported to the Governing Body Board by the Clinical Director at their quarterly meetings in which dates are to be determined and too early to be set based on doctors schedules.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 43C0001016	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 08/20/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Ophthalmology LTD Eye Surgery Center LLC	**6601 S MINNESOTA AVE, STE 100 , SIOUX FALLS, South Dakota, 57108**

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Q0000	INITIAL COMMENTS A recertification health survey for compliance with 42 CFR Part 416, Subpart C; requirements for Ambulatory Surgery Centers (ASC), was conducted from 8/19/24 through 8/20/24. Ophthalmology LTD Eye Surgery Center LLC was found not in compliance with the following requirement: Q109.	Q0000	The IFU for the Lifepak 15 was printed and placed on the crash cart. The IFU includes a daily checklist and inspection tool that we have adopted and will be used daily to check and inspect our defibrillator. A step in the checklist per the IFU requires the use of a "test load". This test load component was obtained by the Stryker Likepak rep on 09/04/24. The daily log was updated to reflect the additional steps that will now be done daily as opposed to monthly. Staff members responsible for checking and inspecting the defibrillator were educated on this new checklist and our updated daily log on 09/05/2024. Our annual competency was also updated to reflect our new daily check and inspection. Our clinical director will do a daily check for one month to ensure 100% compliance with the testing and inspecting of the Likepak 15. The results will be reported to the QA Committee and Governing Board Body at the next scheduled meeting. To monitor compliance thereafter, the daily testing and inspecting of the Likepak 15 will be added to a monthly QAPI tool, which will also be reported to the QA Committee at their scheduled meetings.	10/1/2024
Q0109	EMERGENCY EQUIPMENT CFR(s): 416.44(d) (d) Standard: Emergency equipment. The ASC medical staff and governing body of the ASC coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating room. The equipment must meet the following requirements: (1) Be immediately available for use during emergency situations. (2) Be appropriate for the facility's patient population. (3) Be maintained by appropriate personnel. This STANDARD is NOT MET as evidenced by: Based on observation, interview, policy review, and manufacturer's instructions for use (IFU) review, the provider failed to ensure one of one Lifepak (defibrillator)15's paddles had been checked daily per manufacturer's IFU. Findings include: 1.Observation and interview on 8/20/24 at 7:52 a.m. outside of operating room (OR) 1 with registered nurse (RN) A revealed:	Q0109		

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See reverse for further instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Lindsey Beckstrand	*Clinical Director*	*09/112024*

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 43C0001016	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 08/20/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Ophthalmology LTD Eye Surgery Center LLC	**6601 S MINNESOTA AVE, STE 100 , SIOUX FALLS, South Dakota, 57108**

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Q0109	Continued from page 1 *RN A had been asked to perform the daily monitoring of the defibrillator. *RN A performed the user test (confirms test results print) with the defibrillator plugged in and unplugged from the outlet. -He pressed options. -He selected user test. -He printed the test results. *RN A confirmed testing of the paddles had been conducted monthly per their daily log in the OR. *He stated that testing of the paddles on the defibrillator was not completed daily. *He was unaware of the manufacturer's IFU on how often to test the paddles on the defibrillator. Interview on 8/20/24 at 8:00 a.m. with RN/charge nurse B revealed: *The Lifepak 15 defibrillators were newer machines. *She stated, *When the rep came to teach us, he did not mention we were to check the paddles daily." *She confirmed the IFU on the Lifepak 15 was to check the paddles on the defibrillator daily instead of monthly. *Stated the staff should have been checking the paddles on the defibrillator daily per the manufacturer's IFU. *She stated it would be an easy change to update the OR log and begin checking the defibrillator paddles daily. Interview on 8/20/24 at 11:45 a.m. with RN Infection Prevention/Employee Health C revealed she: *Would have expected staff to follow the manufacturer's IFU for checking the paddles on the defibrillator. *Staff should have been checking the paddles on the defibrillator daily. *Stated, "When in doubt, always follow the IFU." Review of the provider's daily log for the OR daily check documentation for the crash cart revealed a section to document if the monthly paddle test passed	Q0109	09/11/2024 Addendum: QA Committee RN provided the education for all staff who are responsible for testing and inspecting our Lifepak 15 on September 4, 2024. This same QA Committee RN will be responsible for ensuring all Lifepak 15 trained staff members complete the Lifepak 15 competency annually. The Clinical Director will audit the completion of the daily testing and inspection daily (Monday -Thursday) for one full month. This will be reported to the QA Committee at their scheduled meeting on October 16, 2024 by the Clinical Director. The Clinical Director will also report these results to the Governing Body Board at the next scheduled meeting to be held on September 30, 2024 and at the next scheduled quarterly meeting to be determined at a later date, based on doctors schedules. The monthly QAPI tool that incorporates compliancy of completing the daily check will be reported to QA monthly by the RN responsible for this tool, which is completed/reported once a month for the remainder of 2024 as part of our 2024 QAPI Plan.	

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Q0109	Continued from page 2 or failed. Review of the manufacturer's 5/2021 Lifepak 15 Monitor/Defibrillator Operator's Checklist revealed: *"Daily inspection and test is recommended. *Perform standard (hard) paddles check in manual mode." Review of the provider's undated instruction checklist for OR staff revealed the paddle test should have been performed the first day of every month. Review of the provider's 11/17 Crash Cart Checks policy revealed: *"The equipment is checked daily for proper functioning. The findings will be documented on the Crash Cart Checklist. The daily check shall include: -Defibrillator."	Q0109		

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K0000	INITIAL COMMENTS A recertification survey was conducted on 8/20/24 for compliance with 42CFR 416.44(b)(1), requirements for ambulatory surgery centers. Ophthalmology LTD Eye Surgery Center LLC was found not in compliance.	K0000		
K0131 Bldg. 01	Multiple Occupancies CFR(s): NFPA 101 Multiple Occupancies - Sections of Ambulatory Health Care Facilities Multiple occupancies shall be in accordance with 6.1.14. Sections of ambulatory health care facilities shall be permitted to be classified as other occupancies, provided they meet both of the following: * The occupancy is not intended to serve ambulatory health care occupants for treatment or customary access. * They are separated from the ambulatory health care occupancy by a 1 hour fire resistance rating. Ambulatory health care facilities shall be separated from other tenants and occupancies and shall meet all of the following: * Walls have not less than 1 hour fire resistance rating and extend from floor slab to roof slab. * Doors are constructed of not less than 1-3/4 inches thick, solid-bonded wood core or equivalent and is equipped with positive latches. * Doors are self-closing and are kept in the closed position, except when in use. * Windows in the barriers are of fixed fire window assemblies per 8.3. Per regulation, ASCs are classified as Ambulatory Health Care Occupancies, regardless of the number of	K0131	The Clinical Director is working with Automatic Security to place a magnet door retainer unit on this fire wall door. This unit will be wired to a dedicated circuit interfaced electrically with the fire alarm and then release automatically on activation of the Fire Alarm System. This will enable the door to be open and in the event of an emergency, it will close automatically. Upon completed installation, the door will be monitored monthly during the facilities monthly fire pull (activation of the alarm system) for proper function by the Fire Safety Employee. This will be logged in the fire book under our emergency lighting/call light system/ test log. This log will then be audited by the Clinical Director monthly for the next 3 months. 100% compliancy is expected and will be reported to the QA Committee and the Governing Body Board at the next scheduled meeting.	10/1/2024

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Lindsey Beckstrand	Clinical Director	09/05/2024

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K0131 Bldg. 01	Continued from page 1 patients served. 20.1.3.2, 21.1.3.3, 20.3.7.1, 21.3.7.1,42 CFR 416.44 This STANDARD is NOT MET as evidenced by: Based on observation and interview, the provider failed to maintain the fire rating at one randomly chosen location (door connecting the file storage room and the ambulatory surgical center) as required. Findings include: Observation on 8/20/24 at 11:09 a.m. revealed the ninety-minute fire-rated door in the fire-rated wall separating the ambulatory surgery center from the clinic had been held open with a door wedge. That door is required to automatically close and latch into the doorframe. Holding that door open with a door wedge kept that door from providing the required fire separation from the clinic. Interview with the nurse manager at the time of the observation confirmed that finding. She stated the records staff must have placed the wedge there for convenience. She further stated she was unaware that door had been held open with a door wedge.	K0131		

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E0000	Initial Comments A recertification survey for compliance with 42 CFR Part 416, Subpart C, Subsection 416.54, Emergency Preparedness, requirements for ambulatory surgery centers, was conducted on 8/20/24. Ophthalmology LTD Eye Surgery Center LLC was found in compliance.	E0000		

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Lindsey Beckstrand	*Clinical Director*	*09/05/2024*