Indiana State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001074	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 06/08/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SURGERY CENTER OF OPHTHALMOLOGY	7232 ENGLE RD , FORT WAYNE, Indiana, 46804

(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) COMPLETION DATE
S0000	INITIAL COMMENTS This visit was for a state licensure survey of an Ambulatory Surgery Center. Facility Number: 009567 Survey Dates: 06/07/2023 to 06/08/2023 QA: 6/16/2023	S0000		
S0334	QUALITY ASSESSMENT AND IMPROVEMENT CFR(s): 410 IAC 15-2.4-2.2(a)(2) 410 IAC 15-2.4-2.2(a)(2) (2) A process for reporting to the department each reportable event listed in subdivision (1) that is determined by the center's quality assessment and improvement program to have occurred within the center. (b) Subject to subsection (e), the process for determining the occurrence of the reportable events listed in subsection (a)(1) by the center's quality assessment and improvement program shall be designed by the center to accurately determine the occurrence of any of the reportable events listed in subsection (a)(1) within the center in a timely manner. (c) Subject to subsection (e), the process for reporting the occurrence of a reportable event listed in subsection (a)(1) shall comply with the following: (1) The report shall: (A) be made to the department; (B) be submitted not later than fifteen (15) working days after the reportable event is determined to have occurred by the center's quality assessment and improvement program; (C) be submitted not later than four (4) months after	S0334		06/21/2023

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE

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S0334	Continued from page 1 the potential reportable event is brought to the program's attention; and (D) identify the reportable event, the quarter of occurrence, and the center, but shall not include any identifying information for any: (i) patient; (ii) individual licensed under IC 25; or (iii) center employee involved; or any other information. (2) A potential reportable event may be identified by a center that: (A) receives a patient as a transfer; or (b) admits a patient subsequent to discharge; from another health care facility subject to a reportable event requirement. In the event that a center identifies a potential reportable event originating from another health care facility subject to a reportable event requirement, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program. (3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures. (4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law. (d) The center's report of a reportable event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of reportable events occurring within each center. The department's public report will be issued annually. (e) Any serious reportable listed in subsection (a)(1) that: (1) is determined to have occurred within the center between:	S0334		

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S0334	Continued from page 2 (A) January 1, 2009; and (B) the effective date of this rule; and (2) has not been previously reported; must be reported within five (5) days of the effective date of this rule. (Indiana State Department of Health; 410 IAC 15-2.4-2.2) This LICENSURE REQUIREMENT is NOT MET as evidenced by: The RULE: is not met as evidenced by: Based on document review and interview, facility failed to report an Adverse Patient Event to the Indiana Department of Health (IDOH, formerly known as Indiana State Department of Health (ISDH), within 15 days for 1 of 30 (P # 3) patient medical records reviewed. Findings include: 1. Review of Facility Incident Report Log indicated an Adverse Patient Event occurred on 5/03/23 of body part surgery performed not consistent with patient informed consent. 2. Review of Facility Policies and Procedures, POLICY TITLE: 5.9 Adverse Incident Reporting (w/ ISDH guidelines), last approved 1/2023, indicated all reportable events will be reported to the ISDH within 15 days. 3. Medical Record review indicated 1 of 30 patients (P # 3) consented to right eye surgery. On 5/03/23 P # 3 received surgery to the left eye. 4. In interview on 6/07/23, at approximately 12:40 pm, A # 1 (Registered Nurse [RN], Nursing Supervisor) confirmed Patient Adverse Event that occurred on 5/03/23 was not reported to ISDH.	S0334		