STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: **15C0001095**	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED **06/14/2022**

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
KLEINERT KUTZ SURGERY CENTER, LL	**3605 NORTHGATE CT, STE 101 , NEW ALBANY, Indiana, 47150**

(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: 002524 Survey Dates: 6/13/22 to 6/14/22 QA: 7/28/2022	S0000		
S0170	GOVERNING BODY; POWERS AND DUTIES CFR(s): 410 IAC 15-2.4-1 410 IAC 15-2.4-1 (c)(5) (K) Require that the chief executive officer develop and implement policies and programs for the following: (K) Establishing criteria to determine the delineation of privileges. This LICENSURE REQUIREMENT is NOT MET as evidenced by: Based on document review and interview, the governing body failed to ensure that the chief executive officer developed policies and programs establishing criteria to determine delineation of privileges for Medical Staff Fellows who were granted privileges in 1 (one) facility. Findings include: 1. Review of facility policies/procedures/programs, reviewed June 2021, and the Medical Staff (MS) bylaws, reviewed 10/2019, lacked evidence of	S0170		

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

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S0170	Continued from page 1 policies/procedures/programs and/or criteria to determine delineation of privileges for Fellows of the MS. 2. On 6/14/22, in interview at approximately 10:30 AM, A4, Credentials, verified the center did not have documentation of policies/procedures/programs and/or criteria to determine delineation of privileges for the Fellows of the MS.	S0170		
S0172	GOVERNING BODY; POWERS AND DUTIES CFR(s): 410 IAC 15-2.4-1 410 IAC 15-2.4-1 (c)(5) (L) Require that the chief executive officer develop and implement policies and programs for the following: (L) Maintaining personnel records for each employee of the center which include personal data, education and experience, evidence of participation in job related educational activities, and records of employees which relate to post offer and subsequent physical examinations, immunizations, and tuberculin tests or chest x-rays, as applicable. This LICENSURE REQUIREMENT is NOT MET as evidenced by: Based on personnel file review and interview, 15 out of 15 staff: N1 (Housekeeper [HK]), N2 (Registered Nurse [RN]), N3 (RN), N4 (RN), N5 (RN), N6 (RN), N7 (RN), N8 (surgical technician [ST]), N9 (RN), N10 (ST), N11 (ST), N12 (RN), N13 (RN), N14 (RN), N15 (RN) lacked documentation of infection control training; 4 out of 15 staff: N1	S0172		

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S0172	Continued from page 2 (HK), N3 (RN), N12 (RN), N15 (RN) lacked documentation of fire safety training; and 11 out of 15 staff: N2 (RN), N3 (RN), N4 (RN), N5 (RN), N6 (RN), N7 (RN), N9 (RN), N12 (RN), N13 (RN), N14 (RN), N15 (RN) lacked documentation of point of care testing. Findings include: 1. Review of personnel files lacked documentation of infection control training, fire safety training and/or point of care testing for staff N1, N2, N3, N4, N5, N6, N7, N8, N9, N10, N11, N12, N13, N14 and N15. 2. Interview on 6/13/22, at approximately 11:00 am, with A1 (Administrator), indicated no further documentation available to show training was completed.	S0172		
S0228	GOVERNING BODY; POWERS AND DUTIES CFR(s): 410 IAC 15-2.4-1 410 IAC 15-2.4-1(e)(4) The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following: (4) Ensure that the center maintains a written transfer agreement with one (1) or more hospitals for immediate acceptance of patients who develop complications or require postoperative confinement, and that all physicians, dentists, and podiatrists performing surgery in the	S0228		

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S0228	Continued from page 3 center maintain admitting privileges at one (1) or more hospitals in the same county or in an Indiana county adjacent to the county in which the center is located. This LICENSURE REQUIREMENT is NOT MET as evidenced by: Based on document review and interview, the governing body (GB) failed to ensure that for 4 of 4 surgeons/physicians (MD5, MD6, MD7 and/or MD8) performing surgery in the center maintained admitting privileges at one or more hospitals in the same county or in an Indiana county adjacent to the county in which the center is located. Findings include: 1. Review of MS (Medical Staff) credential files lacked documentation of admitting privileges at one or more hospitals in the same county or in an Indiana county adjacent to the county in which the center is located for physicians MD5, MD6, MD7 and/or MD8. 2. On 6/14/22, in interview at approximately 11:30 AM, A4, Credentials, verified that credential files lacked documentation of MD5, MD6, MD7 and/or MD8 having admitting privileges in the same county or in an Indiana county adjacent to the county in which the center is located.	S0228		
S0230	GOVERNING BODY; POWERS AND DUTIES CFR(s): 410 IAC 15-2.4-1 410 IAC 15-2.4-1(e)(5) The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following:	S0230		

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S0230	Continued from page 4 (5) Provide for a periodic review of the center and its operation by a utilization review or other committee composed of three (3) or more duly licensed physicians having no financial interest in the facility. This LICENSURE REQUIREMENT is NOT MET as evidenced by: Based on document review and interview, the governing body failed to ensure periodic review of the center and its operation by a utilization committee (UR) was composed of three (3) or more duly licensed physicians having no financial interest in the facility for 1 (one) facility within the past 4 quarters. Findings include: 1. Review of 4 quarters of facility meeting minutes indicated 3 (three) UR Committee meetings were recorded within the past 4 quarters with the following noted: a. The document titled Medical Staff meeting - Utilization and PEER Review Committee, dated 1/18/22 lacked documentation of the UR committee having been composed of three (3) or more duly licensed physicians having no financial interest in the facility. b. The document titled Medical Staff meeting – Utilization and PEER Review Committee, dated 10/26/21 lacked documentation of the UR committee having been composed of three (3) or more duly licensed physicians having no financial interest in the facility. c. The document titled Medical Staff meeting – Utilization and PEER Review Committee, dated 5/18/21 lacked documentation of the UR committee having been composed of three (3) or more duly licensed physicians having no financial interest in the facility. 2. On 6/14/22, interview at approximately 12:00 PM, A1, Registered Nurse (RN)/Administrator,	S0230		

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S0230	Continued from page 5 verified the UR Committee and meetings as documented above did not include three (3) or more duly licensed physicians having no financial interest in the facility.	S0230		
S0300	QUALITY ASSESSMENT AND IMPROVEMENT CFR(s): 410 IAC 15-2.4-2 410 IAC 15-2.4-2(a) (a) The center must develop, implement, and maintain an effective, organized, center-wide, comprehensive quality assessment and improvement program in which all areas of the center participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following: This LICENSURE REQUIREMENT is NOT MET as evidenced by: Based on document review and interview, the center failed to develop, implement, and maintain an effective, organized, center-wide comprehensive quality assessment and performance improvement (QAPI) program by 1) failing to provide evidence of review/evaluation/measures of 11 of 11 contracted services (biomedical engineering, biohazardous waste, housekeeping, laboratory, laundry/linen, maintenance, radiology, security, discharge, transfer and response to patient emergiencies); and by 2) failing to follow their QAPI plan for: a. Members of the Quality Improvement Committee; b. Assuring implementation of a process for measuring, evaluating, improving, and monitoring its performance; c. Collection of data with systematic measurement; and/or d. Annual evaluation for the past 4 quarters. Findings include: 1. Review of the Quality Assessment and	S0300		

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S0300	Continued from page 6 Performance Improvement Plan, revised 3/2021 and reviewed 6/2022, indicated the following: a. The Center embraces the philosophy of continuous improvement with measureable outcomes. b. The members of the Quality Improvement Committee are the designated members of the Medical Staff (MS), the Director of the Center, a member of Anesthesia, and nursing staff members from members of the clinical areas - preoperative, intraoperative, post operative, Pre-Surgical Testing, Facilities Management, and Registration. It is also responsible for reporting outcomes of all activities to the Governing Board. c. In all areas, the director and/or supervisor is responsible for assuring the implementation of a process for measuring, evaluating, improving, and monitoring its performance. d. Collection of data shall be the basis for determining the level of performance of existing processes and the outcomes resulting from these processes. Measurement shall be systematic, related to relevant dimensions of performance and be of appropriate scope and frequency. e. The effectiveness of the QAPI process is evaluated annually. 2. Review of 4 quarters of meeting minutes titled Medical Staff Meeting/Quality Assurance/Performance Improvement Committee dated 5/18/21, 10/26/21, 1/18/22, and 5/17/22 and facility QAPI documentation: a. Lacked evidence of committee members to have included a member of Anesthesia, and nursing staff members from members of the clinical areas – preoperative, intraoperative, post operative, Pre-Surgical Testing, Facilities Management, and Registration. b. Lacked evidence of review and/or evaluation measures for monitoring of contracted services for biomedical engineering, biohazardous waste, housekeeping, laboratory, laundry/linen, maintenance, radiology, and/or security and lacked evidence of data collection with evaluation outcomes for contracted services. c. The Center lacked evidence of processes for measuring and/or evaluating its performance of	S0300		

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S0300	Continued from page 7 contracted services, the functions of discharge, transfer, and response to patient emergencies and lacked evidence of data collection with systematic measurement. d. The Center lacked evidence of an annual evaluation of the QAPI processes/program within the past 4 quarters. 3. On 6/14/22, in interview beginning at approximately 12:30 PM, A1, Registered Nurse (RN)/Administrator, verified QAPI findings.	S0300		
S0704	MEDICAL STAFF; ANESTHESIA AND SURGICAL CFR(s): 410 IAC 15-2.5-4 410 IAC 15-2.5-4(a)(1) The medical staff shall do the following: (1) Conduct outcome-oriented performance evaluations of its member at least biennially. This LICENSURE REQUIREMENT is NOT MET as evidenced by: Based on document review and interview, the medical staff (MS) failed to conduct biennial outcome-oriented performance evaluations for 12 of 12 members (MD1, MD2, MD3, MD4, MD5, MD6, MD7, MD8, MD9, MD10, AH1, and AH2) within the past 2 years. Findings include: 1. Review of Bylaws of the Medical Staff, reviewed 10/2019, lacked documentation of performance evaluations to be conducted of the MS members. 2. Review of MS credential files lacked documentation of performance evaluations for MS members, Physicians MD1, MD2, MD3, MD4, MD5, MD6, MD7, MD8, MD9, MD10; and CRNAs (Certified Registered Nurse Anesthetists) AH1 and AH2. 3. On 6/14/22, in interview at approximately 11:30	S0704		

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S0704	Continued from page 8 AM, A1, Registered Nurse (RN)/Administrator, indicated the center did not have documentation of outcome-oriented performance evaluations for its' MS members within the past 2 years.	S0704		
S0706	MEDICAL STAFF; ANESTHESIA AND SURGICAL CFR(s): 410 IAC 15-2.5-4 410 IAC 15-2.5-4(a)(2) The medical staff shall do the following: (2) Examine credentials of candidates for appointment and reappointment to the medical staff by using sources in accordance with center policy and applicable state and federal law. This LICENSURE REQUIREMENT is NOT MET as evidenced by: Based on document review and interview, the medical staff (MS) failed to follow their bylaws for examination of credentials of candidates for appointment and reappointment to the MS for 2 of 4 surgeon MS members (MD7 and MD8). Findings include: 1. Review of MS Bylaws, reviewed 10/2019, indicated the following for Basic Qualifications for Membership: Must be Board Certified or Board Eligible in their particular specialty. If they are not Board Certified or Board Eligible in the United States, a letter or certificate must be in their file attesting Board Certification or Eligibility in the country of their specialty education and training. 2. Review of surgeons' credential files lacked evidence of Board Certified or Eligibility in their particular specialty and/or a letter or certificate attesting Board Certification or Eligibility in the country of their specialty education and training for MD7 and MD8.	S0706		

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S0706	Continued from page 9 3. On 6/14/22, in interview at approximately 10:30 AM, A4, Credentials, verified ineligibility of MD7 and MD8 for Board Certification and lack of a letter or certificate in their file attesting Board Certification or Eligibility in the country of their specialty education and training.	S0706		
S0710	MEDICAL STAFF; ANESTHESIA AND SURGICAL CFR(s): 410 IAC 15-2.5-4 410 IAC 15-2.5-4(a)(4) The medical staff shall do the following: (4) Maintain a reasonably accessible hard copy or electronic file for each member of the medical staff, which includes, but is not limited to, the following: (A) A completed, signed application. (B) The date and year of completion of all Accreditation Council for Graduate Medical Education (ACGME) accredited residency training programs, if applicable. (C) A current copy of the individual's: (i) Indiana license showing date of licensure and number or available data	S0710		

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S0710	Continued from page 10 provided by the health professions bureau. A copy of practice restrictions, if any, shall be attached to the license issued by the health professions bureau through the appropriate licensing board. (ii) Indiana controlled substance registration showing number as applicable. (iii) Drug Enforcement Agency registration showing number as applicable. (iv) Documentation of experience in the practice of medicine. (v) Documentation of specialty board certification as applicable. (vi) Documentation of privilege to perform surgical procedures in a hospital in accordance with IC 16-18-2-14(3)(C). (D) Category of medical staff appointment and delineation of privileges approved. (E) A signed statement to abide by	S0710		

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S0710	Continued from page 11 the rules of the center. (F) Documentation of current health status as established by center and medical staff policy and procedure and federal and state requirements. (G) Other items specified by the center and medical staff. This LICENSURE REQUIREMENT is NOT MET as evidenced by: Based on document review and interview, the Medical Staff (MS) failed to maintain member files that included evidence for completion of: 1) documentation of the Accreditation Council for Graduate Medical Education (ACGME) accredited residency training programs for 2 of 4 Fellows appointed to the Medical Staff (MD1 and MD3), 2) documentation of Fellows experience in the practice of medicine for 4 of 4 Fellows (MD1, MD2, MD3 and MD4) and/or: 3) documentation of privilege to perform surgical procedures in a hospital for 4 of 4 Fellows (MD1, MD2, MD3 and MD4) and 2 of 4 surgeons (MD5 and MD8) . Findings include: 1. Review of credential files lacked evidence of completion of Accreditation Council for Graduate Medical Education (ACGME) accredited residency training programs for MS Fellows MD1 and MD3; lacked documentation of Fellows experience in the practice of medicine for MD1, MD2, MD3 and MD4; and lacked documentation of privileges to perform surgical procedures in a hospital for MD1, MD2, MD3, MD4, MD5 and MD8. 2. On 6/14/22, in interview beginning at approximately 10:30 AM, A4, Credentials, verified the above findings.	S0710		
S0728	MEDICAL STAFF; ANESTHESIA AND SURGICAL CFR(s): 410 IAC 15-2.5-4	S0728		

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S0728	Continued from page 12 410 IAC 15-2.5-4(b) (b) The medical staff shall adopt and enforce bylaws to carry out its responsibilities. These bylaws and rules must be as follows: This LICENSURE REQUIREMENT is NOT MET as evidenced by: Based on document review and interview, the medical staff (MS) failed to enforce bylaws to carry out its responsibilities: 1) for meeting requirements of the medical staff (MS) to include, at a minimum, quarterly meetings, and attendance of medical staff members; 2) to ensure a quorum of voting members were present; 3) to include a statement of duties and privileges for each category of the medical staff; and 4) to provide criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges for Fellowship for 1 (one) facility. Findings include: 1. Review of the Medical Staff By-Laws/Rules and Regulations, reviewed 10/2019, indicated the following*: a. The prerogatives of an active staff member shall be to: vote on all matters presented at general and special meetings of the Medical Staff and Committees. b. Regular meetings of the staff shall be held at least annually. c. The presence of 25% of the voting members of the active medical staff shall constitute a quorum at any regular meeting for all regular business. Each member of the staff is encouraged to attend officially called meetings. There are no meeting requirements. d. *The by-laws lacked documentation of a staff category for Fellows and lacked documentation of criteria for determining the privileges to be granted to individual practitioners and a	S0728		

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KLEINERT KUTZ SURGERY CENTER, LL	3605 NORTHGATE CT, STE 101 , NEW ALBANY, Indiana, 47150

(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
S0728	Continued from page 13 procedure for applying the criteria to individuals requesting privileges for Fellowship. 2. Review of the MS roster indicated the Center had 9 (nine) Active staff members, 16 Fellows, and 5 (five) anesthesia providers. 3. Review of 4 quarters of MS meeting minutes dated 8/24/21, 10/19/21, 1/18/22, and 5/17/22 lacked documentation of attendance by any member other than MD8, Medical Director. The minutes indicated the following approvals without a quorum present: a. 8/24/21 minutes: Previous quarter minutes were approved by MD8. Application of MD8 was “approved” and to be presented to the Governing Board (GB). b. 10/19/21 minutes: Previous quarter minutes were approved by MD8. One physician and 2 (two) allied health (Certified Registered Nurse Anesthetists) were “approved” for reappointments. Eighteen (18) “Fellows in Hand Surgery” were “approved” for appointments. c. 1/18/22 minutes: Previous quarter minutes were approved by MD8. One anesthesia provider was recommended to be presented to the GB for approval. d. 5/17/22 minutes: Previous quarter minutes were approved by MD8. 4. On 6/14/22, in interview beginning at approximately 11:30 AM: a. A4, Credentials, verified the MS By-Laws/Rules and Regulations did not include a statement of duties and privileges for each category of the MS nor criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges for Fellowship, nor did the Center have a policy for the above. b. A1, Registered Nurse (RN)/Administrator, verified that By-laws indicated the MS were not required to attend any MS meetings and that approvals/recommendations were made without a quorum present at MS meetings for the past 4 quarters.	S0728		