STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	15C0001185	A. BUILDING 00 B. WING	03/10/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
SOUTH BEND SPECIALTY SURGERY CENTER, LLC	335 FLORENCE AVENUE, STE 1B GRANGER, IN 46530

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Q 0000 Bldg. 00	This visit was for a Recertification survey and a Focused Infection Control Survey. Dates of Survey: 03/8-10/2021 and 03/18/2021 Facility Number: 012996 South Bend Specialty Surgery Center, LLC was found in compliance with the CMS Focused Infection Control Survey for Acute & Continuing Care. QA: 03/22/2021	Q 0000		
Q 0100 Bldg. 00	416.44 ENVIRONMENT The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients. Based on record review, observation, and interview, the facility failed to ensure emergency lighting in 2 of 2 operating rooms where general anesthesia is administered in accordance with NFPA 99 (See tag K323), failed to maintain automatic sprinkler systems in accordance with NFPA 25 (see tag K353), failed to conduct 1 of 4 quarterly shift fire drills during the most recent 12 month time period. LSC 21.7.1.6 requires drills to be conducted quarterly on each shift under varied conditions (see tag K712), failed to maintain 1 of 1 Emergency Power Standby System in accordance with NFPA 110, Standard for Emergency and Standby Power Systems (see tag K918) and failed	O 0100	Tag K323 Emergency battery back-up lighting test was conducted on 3/23/21 and during inspection 2 lights failed in OR 2 light 1 and Procedure room light 1. Vendor was contacted to repair and came out for inspection on 3/30/21 and repaired Procedure room light 1 and consultation room failed. On 3/31/21 vendor was on site to repair OR 2 and consultation room but needed to order parts. The parts have been ordered and expected repair by 4/23/21.	04/23/2021

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

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	to ensure an annual fuel quality test was performed for the facility's diesel powered generator (see tag K918). The cumulative effect of this systemic problem resulted in the facility's inability to ensure that all locations from which it provides services are constructed, arranged and maintained to ensure the provision of quality health care in a safe environment.		Surgical Coordinator will inspect emergency lights after repair and to ensure it does not happen again will perform monthly and annual test and document on a log. Policy has been updated with monthly and annual testing. Tag K353 Backflow testing was performed on 3/18/21 by Mishawaka Utilities and during this inspection on of the backflows failed. The vendor was called to repair the backflow and repair was completed on 3/25/21. The vendor forwarded the report of repair to Mishawaka Utilities on 3/25/21. The Surgical Coordinator will maintain fire riser sprinkler system monthly logs. The Director will ensure that the backflow test is performed yearly by Mishawaka Utilities. Tag K712 The Director has implemented monthly staff meetings to include required education, drills including fire and competencies to ensure all requirements are met. The Director has pre-scheduled all meetings on the calendar. A fire drill was conducted on 2/17/21 and the next fire drill is schedule with the monthly meeting in June. Tag K918 The vendor was out on 3/25/21 and performed a 4 hour load generator test and an annual fuel test. The contract will be revised to include the 4hr load every 3 years and annual fuel test. The	

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			policy has been updated. The Director has added when this test should be conducted on the calendar to ensure this 4 hour generator load requirement takes place every 3 years.	
Q 0101 Bldg. 00	416.44(a)(1) PHYSICIAL ENVIRONMENT The ASC must provide a functional and sanitary environment for the provision of surgical services. Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area. Based on record review, observation, and interview, the facility failed to ensure emergency lighting in 2 of 2 operating rooms where general anesthesia is administered in accordance with NFPA 99. NFPA 99, Health Care Facilities Code, 2012 Edition, Section 6.3.2.2.11.1 states one or more battery-powered lighting units shall be provided within locations where deep sedation and general anesthesia is administered. The lighting level of each unit shall be sufficient to terminate procedures intended to be performed within the operating room. The sensor for units shall be wired to the branch circuit(s) serving general lighting within the room. Units shall be capable of providing lighting for 90 minutes and shall be tested monthly for 30 seconds and annually for 30 minutes. Section 3.3.17 defines battery-powered lighting units as individual unit equipment for backup illumination consisting of a rechargeable battery, battery-charging means, provisions for one or more lamps mounted on the	O 0101	Tag K323 Emergency battery back-up lighting test was conducted on 3/23/21 and during inspection 2 lights failed in OR 2 light 1 and Procedure room light 1. Vendor was contacted to repair and came out for inspection on 3/30/21 and repaired Procedure room light 1 and consultation room failed. On 3/31/21 vendor was on site to repair OR 2 and consultation room but needed to order parts. The parts have been ordered and expected repair by 4/23/21. Surgical Coordinator will inspect emergency lights after repair and to ensure it does not happen again will perform monthly and annual test and document on a log. Policy has been updated with monthly and annual testing.	04/23/2021

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	equipment, or with terminals for remote lamps, or both, and relaying device arranged to energize the lamps automatically upon failure of the supply to the unit equipment. This deficient practice could affect two patients and staff in operating rooms where general anesthesia or life support equipment is used. Findings include: During record review with the Director and Surgical Coordinator on 03/18/2021 at 12:02 p.m. the facility was unable to provide documentation of testing for battery powered emergency lighting in two operating rooms. Based on interview at the time of record review, the Director and the Surgical Coordinator confirmed that general anesthesia is used. Additionally, they were unsure if the operating rooms had emergency lighting, and could not provide any documentation of testing. During a subsequent tour of the facility from 12:30 p.m. and 12:50 p.m., 4 battery powered emergency lights were located in Operating Room #1 and Operating Room #2. Based on interview at the time of observation, the Director and the Surgical Coordinator agreed that each operating room contained 4 battery powered emergency lights. This deficient finding was reviewed with the Director at the time of exit.			
Q 0104 Bldg. 00	416.44(b)(1)-(3) SAFETY FROM FIRE (b) Standard: Safety from fire. (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, and must proceed in accordance with the Life			

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	Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4). (2) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients. (3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC. 1) Based on record review and interview, the facility failed to maintain automatic sprinkler systems in accordance with NFPA 25. LSC 9.7.5 requires all sprinkler systems shall be inspected, tested, and maintained in accordance with NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems. NFPA 25, 2011 Edition, Section 4.1.4.1 states the property owner or designated representative shall correct or repair deficiencies or impairments that are found during the inspection, test and maintenance required by this standard. Corrections and repairs shall be performed by qualified maintenance personnel or a qualified contractor. NFPA 25, 4.3.1 requires records shall be made for all inspections, tests, and maintenance of the system components and shall be made available to the authority having jurisdiction upon request. This deficient practice could affect all patients, staff, and visitors in the facility.	Q 0104	Tag K353 Backflow testing was performed on 3/18/21 by Mishawaka Utilities and during this inspection on of the backflows failed. The vendor was called to repair the backflow and repair was completed on 3/25/21. The vendor forwarded the report of repair to Mishawaka Utilities on 3/25/21. The Surgical Coordinator will maintain fire riser sprinkler system monthly logs. The Director will ensure that the backflow test is performed yearly by Mishawaka Utilities. Tag K712 The Director has implemented monthly staff meetings to include required education, drills including fire and competencies to ensure all requirements are met. The	03/25/2021

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	Findings include: During record review with the Director on 03/18/2021 at 11:10 a.m., Sprinkler vendor documentation dated 03/18/2021, the relief valve of the sprinkler system backflow device did not open. Based on interview at the time of record review, the Director stated that a plumbing contractor had already been contacted to make the repair, however it had not yet been scheduled. This deficient finding was reviewed with the Director at the time of exit. 2) Based on record review and interview, the facility failed to conduct 1 of 4 quarterly shift fire drills during the most recent 12 month time period. LSC 21.7.1.6 requires drills to be conducted quarterly on each shift under varied conditions. The 1135 Waiver provided for the COVID-19 Public Health Emergency allows for documented approved training in place of fire drills. This deficient practice affects all patients and staff. Findings include: During record review with the Director on 03/18/2021 at 11:12 p.m., the facility was unable to provide documentation of a fire drill or approved training for the fourth quarter of 2020. Based on interview at the time of record review, the Director agreed the fourth quarter fire drill was not completed and approved training was not completed in it's place. This deficient finding was reviewed with the Director at the time of exit.		Director has pre-scheduled all meetings on the calendar. A fire drill was conducted on 2/17/21 and the next fire drill is schedule with the monthly meeting in June.	

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Q 0108 Bldg. 00	416.44(c) BUILDING SAFETY (c) Standard: Building Safety. Except as otherwise provided in this section, the ASC must meet the applicable provisions and must proceed in accordance with the 2012 edition of the Health Care Facilities Code (NFPA 99, and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6). (1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an ASC. (2) If application of the Health Care Facilities Code required under paragraph (c) of this section would result in unreasonable hardship for the ASC, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients. 1) Based on record review and interview, the facility failed to maintain 1 of 1 Emergency Power Standby System in accordance with NFPA 110, Standard for Emergency and Standby Power Systems, Section 8.4.9, as required by NFPA 99 Health Care Facilities Code, Section 6.4.1.1.6.1. NFPA 110 Section 8.4.9 states that all Level 1 Emergency Power Systems shall be tested at least once within every three years. Where the assigned class is greater than 4 hours, it shall be permitted to terminate the test after 4 hours. NFPA 99 Section 6.4.1.1.6.1 states that Type 1 and Type 2 essential electrical system power sources shall be classified at Type 10, Class X, Level 1 generator sets. This deficient practice could affect all building occupants.	Q 0108	Tag K918 The vendor was out on 3/25/21 and performed a 4 hour load generator test and an annual fuel test. The contract will be revised to include the 4hr load every 3 years and annual fuel test. The policy has been updated. The Director has added when this test should be conducted on the calendar to ensure this 4 hour generator load requirement takes place every 3 years.	03/25/2021

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	Findings include: During record review with the Director on 03/10/2021 at 12:05 p.m., the facility provided documentation for testing of the emergency generator, however could not provide documentation of a three year 4 hour test. This was confirmed by the Director. This deficient finding was reviewed with the Director at the time of exit. 2) Based on record review and interview, the facility failed to ensure an annual fuel quality test was performed for the facility's diesel powered generator. NFPA 99, Health Care Facilities Code, 2012 Edition Section 6.5.4.1.1.2 states Type 2 EES (Essential Electrical System) generator sets shall be inspected and tested in accordance with Section 6.4.4.1.1.3. Section 6.4.4.1.1.3 states maintenance shall be performed in accordance with NFPA110, Standard for Emergency and Standby Power Systems, 2010 Edition, Chapter 8. NFPA 110, Section 8.3.8 states a fuel quality test shall be performed at least annually using tests approved by ASTM standards. This deficient practice could affect all residents. Findings include: Based on record review with the Director on 03/18/2021 at 12:15 p.m., no documentation of an annual fuel quality test for the diesel generator was available for review. Based on interview at the time of records review, the Director stated the facility does have a diesel generator but was unaware of the fuel quality testing requirements. This deficient finding was reviewed with the Director at the time of exit.			

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S 0000 Bldg. 00		S 0000		
	This visit was for a State licensure survey Facility Number: 012996 Dates of Survey: 3/8/2021 to 3/10/2021 QA: 3/16/21			
S 0110 Bldg. 00	410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (a)(5) The governing body shall do the following: (5) Review, at least quarterly, reports of management operations, including, but not limited to, quality assessment and improvement program, patient services provided, results attained, recommendations made, actions taken, and follow-up. Based on document review and interview, the Ambulatory Surgery Center's (ASC) Governing body, failed to ensure a review Quality assessment (QA), at least quarterly for 3 of 4 quarters for calendar year 2020. Findings: 1. Review of established ASC policy titled: "Legal Responsibility of the Governing Board", indicated under POLICY, point 6, "Assuring that	S 0110	Utilization meeting for 3rd and 4th QTR of 2020 was conducted 3/22/21 and approved at the 3/24/21 board meeting Quality meeting for 3rd and 4th QTR of 2020 was conducted 3/23/21 and approved at the 3/24/21 board meeting. These meetings have been pre-scheduled for the remainder of the year by the Director to ensure	03/24/2021

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	the quality of care is evaluated". Last revised 3/2018. 2. Review of established ASC policy titled: "Quality and Performance Improvement", indicated under QA activities (g), "The results of the quality assurance program shall be submitted to the governing board quarterly". Last revised 1/2018. 3. Review of Governing Board meeting minutes for calendar year 2020 and thus far 2021, indicated that QA was reviewed in 2nd quarter meetings; with no QA reviewed in 1st, 3rd or 4th quarters 2020. 4. In interview with staff member A # 1 (Administrator - Director), on 3/10/2021 at approximately 3:50 pm, confirmed the following: A. That the governing board meets usually every month; although QA committee only met once in November of 2020. B. Not able to be sure how many times QA was reviewed by the governing board in 2020, and acknowledged missing QA from 2020.		that they do occur. 1st and 2nd QTR Utilization meeting was conducted 9/1/2020 1st and 2nd QTR Quality meeting was conducted 11/20/20 "Legal Responsibility of the Governing Board policy will be reviewed at the next board meeting. Policy review for all policies is ongoing.	
S 0153 Bldg. 00	410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(c) (5) (C) Require that the chief executive officer develop and implement policies and programs for the following: (C) Orientation of all new employees, including contract and agency personnel, to applicable center and personnel policies. Based on document review and interview, the	S 0153	The staff are Beacon Health	04/05/2021

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	chief executive officer failed to ensure policies and programs for the orientation of eight of eight employees reviewed were implemented (P1, P10, A1, P12, P13, P14, P15, and P16). Findings included: 1. Review of "Orientation and Training" policy/procedure number 3.16, last revised 2-6-2017, read: "The employee will meet with the Administrator to complete new hire paperwork and for orientation to the Employee Handbook..." and "The supervisor will explain and give the employee a copy of...Orientation Manual - General and Department/Job Specific..." and "Initial orientation and training shall be...completed within thirty (30) days of commencement of employment..." and "After orientation is completed, the initial orientation and training checklist, based on the position description is signed and dated by the employee and filed permanently in the employee's personnel file..." 2. Review of personnel documents indicated the following: a. There was no documentation of initial orientation for the following staff: P10 (Registered Nurse (RN), hire date 6-21-2020); A1 (Administrator-Director, hire date 1-31-2019); P12 (RN, hire date 5-25-2020); P13 (Surgical Technician, hire date 4-6-2020); and P16 (Surgical Coordinator, hire date 1-31-2019). b. There was no documentation of an orientation checklist "based on the position description" for the following staff: "P1 (RN, hire date 11-10-2019); P10; A1; P12; P14 (Surgical Technician, hire date 1-31-2019); P15 (RN, hire date 1-10-2020); and P16. 3. In interview on 3-9-2021 at 11:00 AM, A1		System employees. The Director is creating a shadow employee file. Beacon Health System will only allow the Surgery Center to keep certain documents due to employee privacy. Some educational and human resource information i.e. employee handbook is on the Beacon Health System NetLearning web-based software. An initial orientation checklist has been created by the Surgical Coordinator. A training check sheet for clinical staff has been created by the Surgical Coordinator. Job specific competencies for clinical staff has been created by the Surgical Coordinator. Non-clinical staff job competencies has been created by the Director. Some yearly education requirements are provided by Beacon Health System on their NetLearning web-based software. The Director has implemented keeping a copy in the shadow employee file. A employee shadow file checklist has been created by the Director to ensure all of the information is obtained in the shadow file. Creating the employee files is ongoing.	

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	acknowledged there was no documentation of initial orientation for P10, A1, P12, P13, and P16 and indicated there was no orientation "based on the position description" provided the following staff: P1, P10, A1, P12, P14, P15, and P16.			
S 0156 Bldg. 00	410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (E) Require that the chief executive officer develop and implement policies and programs for the following: (E) Maintenance of current job descriptions with reporting responsibilities for all personnel and annual performance evaluations, based on a job description, for each employee providing direct patient care or support services, including contract and agency personnel, who are not subject to a clinical privileging process. Based on document review and interview, the chief executive officer failed to maintain current job descriptions for one of eight personnel reviewed (P16). Findings included: 1. Review of "Definition and Delineation of Personnel Functional Responsibilities and Authority" policy/procedure number 3.17, last revised 2-6-2017, read: The Administrator will keep Job (sic) descriptions up to date..." and "Job descriptions will define and delineate the following...Position Description...Key responsibilities of the position..."	S 0156	Job descriptions for the Safety Officer, Quality Assurance and Risk Management and Infection Control were created by the Director. The Staff are Beacon Health System employees. The Director has created a checklist for new hires to keep a shadow employee file to ensure job descriptions and any other required documents are maintained. Some information is housed on employees at Beacon Health System.	03/29/2021

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	2. Review of personnel records indicated P16, hire date 1-31-2019, was the Surgery Coordinator. The job description for P16 did not include duties and responsibilities for an Infection Control Officer, Safety Officer, or Quality Assurance Coordinator, nor was there separate Infection Control Officer, Safety Officer, or Quality Assurance Coordinator job descriptions in P16's personnel record. 3. In interview on 3-9-2021 at 2:50 PM, A7, Registered Nurse, indicated P16 was the Infection Control Officer and Safety Officer. 4. In interview on 3-10-2021 at 1:50 PM, A1, Administrator-Director indicated P16 was the Infection Control Officer, Safety Officer, and Quality Assurance Coordinator. A1 confirmed P16 did not have written job descriptions or written duties and responsibilities as the Infection Control Officer, Safety Officer, and Quality Assurance Coordinator.			
S 0164 Bldg. 00	410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (H) Require that the chief executive officer develop and implement policies and programs for the following: (H) A post offer physical examination and employee health monitoring in accordance with the center's infection control program. Based on document review and interview, the chief executive officer failed to develop policies and programs for a post offer physical examination for eight of eight personnel reviewed	S 0164	The staff are Beacon Health System employees. The surgery center does not conduct any human resource offers in-house.	04/23/2021

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	(P1, P10, A1, P12, P13, P14, P15, and P16). Findings included: 1. Review of personnel records indicated there was no documentation of a post offer physical examination for the following personnel: P1 (Registered Nurse (RN), hire date 11-10-2019); P10 (RN, hire date 6-21-2020), A1 (Administrator-Director, hire date 1-31-2019), P12 (RN, hire date 5-25-2020), P13 (Surgical Technician, hire date 4-6-2020), P14 (Surgical Technician, hire date 1-31-2019), P15 (RN, hire date 1-29-2020), and P16 (Surgical Coordinator, hire date 1-31-2019. 2. A request for the policy regarding post offer physical examinations was made on 3-9-2020 at 12:26 PM. A policy was not provided prior to survey exit.		The Director has created a check list of what documents are needed to compile a shadow employee file. Some employee information is housed at Beacon Health System. The Director has obtained the Post-exam physical policy from Beacon Health System and is in the process of completing all employee shadow files. On the checklist and in the employee shadow file the Director will ensure a post offer physical has been completed by Beacon Health System. The checklist was created by the Director to ensure this does not happen again and an employee shadow file is current.	
S 0300 Bldg. 00	410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 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: Based on document review and interview, the Ambulatory Surgery Center (ASC), failed ensure a Quality Assessment (QA) program that was ongoing for calendar year 2020.	S 0300	The QA meeting was held 3/23/21. The minutes were approved by the Board of Directors on 3/24/21. The Director has implemented quarterly meetings	03/24/2021

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	Findings: 1. In review of established ASC policy titled: "Quality and Performance Improvement", indicated under plan, (b), "The Administrator is responsible for coordinating the quality assurance program and shall provide for ongoing monitoring". Last reviewed 1/2018. 2. In review of committee meeting minutes; with only 1 meeting held in November 2020; it cannot be determined that the QA program is an ongoing program. 3. In interview with staff member A # 1 (Administrator - Director), on 3/9/2021, at approximately 10:35 am, confirmed the following: A. That there was only 1 meeting held in November 2020; with data from 1st and 2nd quarters of 2020 submitted, and "not sure if will find anymore". B. No meetings in 1st, 2nd or 3rd quarters in 2020. 4. No other documentation and/or communication was provided prior to exit.		and placed them on the Directors calendar to ensure they take place.	
S 0414 Bldg. 00	410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(1) (f) The center shall establish a committee to monitor and guide the infection control program in the center as follows: (1) The infection control committee shall be a center or medical staff committee, that meets at least quarterly, with membership that			

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	includes, but is not limited to, the following: (A) The person directly responsible for management of the infection surveillance, prevention, and control program as established in subsection (d). (B) A representative from the medical staff. (C) A representative from the nursing staff. (D) Consultants from other appropriate services within the center as needed. Based on document review and interview, the Ambulatory Surgery Center's (ASC) Infection Control (IC) Committee, failed to meet at least quarterly for calendar year 2020. Findings: 1. In review of QA, IC, Patient Safety and Environmental Safety Committee meeting minutes for calendar year 2020, the following was noted: A. That there was one meeting held in November 2020. B. That there was no meeting minutes for 1st, 2nd or 3rd quarters of 2020. 2. In interview with staff member A # 1 (Administrator - Director), on 3/9/2021, at approximately 10:36 am, confirmed the following: A. That there was only 1 meeting held in 2020. B. That meetings are to be held quarterly, and IC is reported at QA meeting; IC part of QA. 3. No other documentation was provided prior to exit.	S 0414	Quality/infection control/patient safety and environmental safety meeting for 3rd and 4th QTR of 2020 was conducted 3/23/21 and approved at the 3/24/21 board meeting. These meetings have been pre-scheduled for the remainder of the year by the Director to ensure that they do occur. 1st and 2nd QTR Quality/Infection control/patient safety and environmental safety meeting was conducted 11/20/20	03/24/2021

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S 0424 Bldg. 00	410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.4-1(f)(2)(D) The infection control committee responsibilities must include, but are not limited to: (D) Written reports of quarterly meetings. Based on document review and interview, the Ambulatory Surgery Center's (ASC) Infection Control (IC) Committee, failed to ensure written reports of quarterly meetings for calendar year 2020. Findings: 1. In review of QA, IC, Patient Safety and Environmental Safety Committee meeting minutes for calendar year 2020, the following was noted: A. That there was one meeting held in November 2020. B. That there was no meeting minutes for 1st, 2nd or 3rd quarters of 2020. 2. In interview with staff member A # 1 (Administrator - Director), on 3/9/2021, at approximately 10:36 am, confirmed the following: A. That there was only 1 meeting held in 2020. B. That meetings are to be held quarterly, and IC is reported at QA meeting; IC part of QA. 3. No other documentation was provided prior to exit.	S 0424	Infection Control/quality/safety and environmental meeting 1st and 2nd QTR 2020 was conducted November 20, 2020. 3/23/21 Infection Control/quality meeting for 3rd and 4th Qtr was conducted 3/23/21 and approved in the board meeting minutes on 3/24/21. The Director has pre-scheduled all meetings for the remainder of the year to ensure that moving forward these meetings are conducted.	03/24/2021
S 0446 Bldg. 00	410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(x) The infection control committee			

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	responsibilities must include, but are not limited to: (E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following: (x) A program of linen management. Based on document review and interview, the Ambulatory Surgery Center (ASC) failed to ensure a program - policy for linen management. Findings: 1. Review of ASC's Infection Control policies & procedures, indicated a lack of an established linen program - policy. 2. In interview with staff member A # 1 (Administrator - Director) and staff member A # 7 (OR {Operating Room} Charge Nurse) on 3/9/2021 and 3/10/2021, at approximately 1:40 pm, and approximately 10:50 am, confirmed the following: A. Only have a contract for Linen service. B. Not aware of a linen management policy. 3. No other documentation was provided prior to exit.	S 0446	The Surgical Coordinator revised the linen management policy. The policy includes how the linen is stored, where in-house it is stored and how it is transported and processed by the linen vendor. The policy will be approved at the next board meeting.	03/26/2021
S 0534 Bldg. 00	410 IAC 15-2.5-2 LABORATORY SERVICES 410 IAC 15-2.5-2(j) (j) The center shall develop, implement, and maintain written quality control and quality assurance policies and procedures for complexity of testing performed that are			

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	consistent with and include all standards found in 42 CFR 493. Based on document review and interview, the center failed to implement written quality control and quality assurance policies and procedures for two of two waived tests performed (glucometer and urine pregnancy). Findings included: 1. Review of "Waived Testing," policy/procedure number 12.06, last revised 2-6-2017, read: "Glucometer test high/low quality control will be performed and documented according to recommended manufacturer's guidelines..." and "The quality control log will be maintained by the Administrator or designee and will list...Calibration control...Quality control...Low and high range..." 2. Review of manufacturer's instructions indicated the following: a. "EvenCare G3," copyright 2013 read: "Record the date on the bottle when opening a new bottle of control solution. Discard any unused control solution three months after the opening date..." and "Record the date on the bottle when you open a new bottle of test strips. Discard any unused test strips six months after opening..." and "The following products have been approved for cleaning and disinfecting the EvenCare G3 Meter: Dispatch Hospital Cleaner Disinfectant Towels with Bleach (EPA Registration Number: 56392-8)...Medline Micro-Kill+ Disinfecting, Deodorizing, Cleaning Wipes with Alcohol (EPA Registration Number: 59894-10-37549)...Clorox Healthcare Bleach Germicidal and Disinfectant Wipes (EPA Registration Number: 67619-12)...Medline Micro-Kill Bleach Germicidal Bleach Wipes (EPA	S 0534	Glucometer Quality Control log updated by the Surgical Coordinator to include discarded of controls after 90 days. The discard date of test strips after 180 days. Pregnancy test policy updated by the Surgical Coordinator to include directions of pregnancy test use along with purchase of timer for reading the results 3-4 minutes after starting the test. Surgical Coordinator placed a quick reference guide in log book. These policy revisions will be officially approved by the Board of Managers at the next board meeting.	03/26/2021

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	Registration Number 69687-1)..." b. "hCG Cassette Rapid Test" by Cardinal Health, copyright unknown, read: "Hold the dropper vertically and transfer 3 full drops of urine (approx. 100 µL) to the specimen well..." and "Read the result at 3-4 minutes..." 3. Review of "Glucometer Quality Control" logs indicated the following: a. Low control, lot number 16818043102, expiration date 4-16-2020, was in use between 12-13-2019 and 5-11-2020. b. Low control, lot number 1681923102, expiration date 12-2-2021, was in use between 8-24-2020 and 12-3-2020. c. High control, lot number 1681923202, expiration date 12-2-2021, was in use between 8-24-2020 and 12-3-2020. d. Test strip, lot number 1681903303 was in use between 12-13-2019 and 6-16-2020. e. Test strip, lot number 16819093008 was in use between 6-8-2020 and 12-18-2020. f. Test strip, lot number 16819093005 was in use between 6-23-2020 and 1-26-2021. g. The log documented the low control acceptable range for test strip lot number 1681903303 to be "40-70" on 12-13-2019; "45-75" on 1-31-2020; and "45-76" on 6-16-2020. h. The log documented the low control acceptable range for test strip lot number 16819073302 to be "43-73" on 1-31-2020; and "43-75" on 4-9-2020. i. The log documented the high control acceptable range for test strip lot number 1681903303 to be "178-240" on 12-13-2029; "176-238" on 1-31-2020; and "173-235" on 5-11-2020. j. The log documented the high control acceptable range for test strip lot number 16819073302 to be "173-235" on 4-9-2020 and			

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	"176-238" on 6-1-2020. k. The log documented the high control acceptable range for test strip lot number 16819093008 to be "176-238" on 6-8-2020 and "172-232" on 9-23-2020. 4. In interview on 3-9-2021 at 2:40 PM, P12, Registered Nurse (RN), indicated the center was using alcohol swabs to clean the glucometer in between use with each patient. P12 further indicated at 2:45 PM on the same date urine pregnancy testing was performed by adding three or four drops of urine to the cassette and reading results in less than one minute. P12 indicated the testing time for urine pregnancy testing was not monitored using a timer. 5. In interview on 3-10-2021 at 9:55 AM, A2, RN, acknowledged the glucometer logs indicate controls and test strips were used beyond their expiration date when opened and the logs indicated different control acceptable ranges on different dates for the same glucometer test strip lot number. A2 further indicated urine pregnancy testing was performed by adding three drops of urine to the cassette and reading the results at three minutes. A2 indicated the testing time for urine pregnancy testing was not monitored using a timer and stated results are often read after three minutes because they start the test and then prepare the patient for surgery before reading the test results.			
S 1152 Bldg. 00	410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(3)(B) (b) The condition of the physical plant and the overall center			

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	environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows: (3) Provision must be made for the periodic inspection, preventive maintenance, and repair of the physical plan and equipment by qualified personnel as follows: (B) All mechanical equipment (pneumatic, electric, sterilizing, or other) must be on a documented maintenance schedule of appropriate frequency in accordance with acceptable standards of practice or the manufacturer's recommended maintenance schedule.			
	Based on document review and interview, the center failed to maintain the medical gas and vacuum pressures within acceptable limits for 10 of 40 dates reviewed. Findings included: 1. Review of "Medical Gas and Vacuum Pressure Log" indicated the following: a. The oxygen pressure was to be maintained between 40 and 60 pound-force per square inch (PSIG). b. The oxygen pressure was not within acceptable limits on 2-2-2021 (28 PSIG in the operating room (OR)). Corrective action was not documented. c. The vacuum pressure was to be maintained between 12 and 20 inches of mercury (INHG). d. The vacuum pressure was not within acceptable limits on 1-4-2021 (22 INHG in the post-anesthesia care unit (PACU) and 23 INHG in	S 1152	The Surgical Coordinator spoke with the vendors technician and reviewed procedure for out of range values for the Medical gas and vacuum. Surgical Coordinator received correct out of range values from the vendors technician. The Medical Gas and Vacuum pressure log has been updated. The Surgical Coordinator updated the policy to include the procedure for out of range alarm for medical gas and vacuum. The Surgical Coordinator spoke to vendor to get a quote to set up an in-service with the vendor. No date set as of yet, but in the process. the Director will receive the quote and have this in-service set up. The revised policy will approved at the next board	03/30/2021

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	the OR); 1-5-2021 (23 INHG in the OR); 1-6-2021 (24 INHG in the PACU and 23 INHG in the OR); 1-8-2021 (24 INHG in both the PACU and OR); 1-13-2021 (28 INHG in both the PACU and OR);1-25-2021 (27 INHG in the PACU and 28 in the OR); 2-15-2021 (29 INHG in the OR); 2-25-2021 (28 INHG in the PACU and 25 INHG in the OR); 3-2-2021 (27 INHG in the PACU and 29 INHG in the OR); and 3-10-2021 (28 INHG in both the PACU and OR). Corrective action was not documented. 2. In interview on 3-10-2021 at 2:05 PM, A1, Administrator-Director, acknowledged the above findings and indicated there was no policy/procedure with regards to corrective action and monitoring of oxygen pressure and vacuum pressure.		meeting.	
S 1188 Bldg. 00	410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(4) (c) A safety management program must include, but not be limited to, the following: (4) A written fire control plan that contains provisions for the following: (A) Prompt reporting of fires. (B) Extinguishing of fires. (C) Protection of patients, personnel, and guests. (D) Evacuation. (E) Cooperation with firefighting authorities. (F) Fire drills. Based on document review and interview, the	S 1188	Fire drills are to be conducted	03/22/2021

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	Ambulatory Surgery Center (ASC) failed to ensure the Emergency plan was followed for conducting fire drills in 1 of 4 quarters for calendar year 2020 into 2021. Findings: 1. Review of ASC policy titled: Emergency Plan, indicated under PROCEDURE, page 2, # 4. "Fire drills are conducted quarterly." Last revised 2/2017, last reviewed 1/2018. 2. Review of ASC's Fire Drill Evaluation Forms for calendar year 2020 and thus far 2021, indicated the following: A. Fire Drills were conducted on 2/17/2021, 7/23/2020 and 4/28/2020. B. No documentation was found for a 4th quarter fire drill for 2020. 3. In Interview with ASC staff member A # 1 (Administrator - Director), on 3/9/2021 at approximately 9:41 am, confirmed that there was not a fire drill conducted at the ASC for 4th quarter 2020. 4. No other documentation was provided prior to exit.		quarterly. Our 1st fire drill of 2021 was conducted 2/7/21 The Director has implemented monthly staff meetings to go over education, competencies and drills that may be due.	
S 1196 Bldg. 00	410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAc 15-2.5-7(c)(5) (c) A safety management program must include, but not be limited to, the following: (5) Maintenance of written evidence of regular inspection and approval by			

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	state or local fire control agencies in accordance with center policy and state and local regulations. Based on document review and interview, the Ambulatory Surgery Center (ASC), failed to ensure written evidence of a regular local or state fire control inspection in accordance with policy, and state and local regulations. Findings include: 1. Review of ASC policy titled: Emergency Plan, indicated under PROCEDURE, page 2, # 8. "The facility shall request, at least annually, that the local fire code authority perform a fire inspection and the request shall be documented. The date of the inspection, the results, and the inspector or agent conducting the inspection shall be documented." Last revised 2/2017, last reviewed 1/2018. 2. Review of fire/building inspections for the ASC, indicated that the last Fire/Building Inspection was conducted 7/23/2018. 3. In interview with ASC staff member A # 1 (Administrator-Director) on 3/9/2021 at approximately 9:42 am, confirmed the following: A. That the facility has not had a fire marshal inspection since July 2018. B. Was not aware that had to have them; "to come out every year". 4. No other documentation was provided prior to exit.	S 1196	Fire Marshal came for an inspection. The Director has a report of pass. Conversation with the Fire Marshal -he will come out every year if needed but ASC would need to call the Fire Marshal Office to set this visit up each year. The Director is now aware of this guideline and has noted on the calendar as a reminder each year to set up appointment.	03/23/2021
S 1220 Bldg. 00	410 IAC 15-2.5-8 RADIOLOGY SERVICES 410 IAc 15-2.5-8(d)			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	15C0001185	A. BUILDING 00 B. WING	03/10/2021

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	(d) Written policies and procedures must be developed, implemented, and maintained and made available to personnel. Based on document review and interview, the center failed to ensure radiology policies and procedures were implemented from 4-25-2019 to date of survey. Findings included: 1. Review of "Employee Safety" policy/procedure number 13.06, revised 2-6-2017, indicated radiation dosimetry badges were "read by Mirion Technologies quarterly to document individual radiation exposure..." and "A staff person is assigned to review and maintain records of individual radiation exposure..." The policy/procedure did not indicate radiation dose limits for employees. 2. Review of "Safety and Maintenance" policy/procedure number 13.04, revised 2-6-2017 indicated lead aprons, thyroid shields, and gloves were "visually checked before each use for cracks or flaws..." but did not indicate the lead aprons were monitored for cracks and flaws in the lead lining. 3. Review of "Occupational Radiation Exposure" reports from Mirion Technologies indicated the following: a. A report dated 12-17-2020 indicated dosimetry badges were received on 11-30-2020. The "Monitoring Period" of the badges was 1-25-2020 to 10-24-2020. b. A report dated 8-10-2020 indicated dosimetry badges were received 7-20-2020. There were several "Monitoring" periods of the badges that	S 1220	The Surgical Coordinator updated the Radiation Policy to include the radiation dose limits per quarter, annual and lifetime exposure. The policy will also include that xray lead are visually checked before each use and monitored for cracks and flaws in the lead lining. Protective lead devices will be tested in compliance with federal, state and local laws and regulations. All lead aprons and collars will be physically examined for defects for perforations and thinning on an annual basis and upon request. An annual visual/fluoroscopic inspection procedure has been created in the policy. The criteria for rejection was created in the policy as well. A Radiation Officer has been named and was approved at the 3/24/21 board meeting.	03/30/2021

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	ranged between 4-25-2019 and 1-24-2020 4. In interview on 3-10-2021 at 10:08 AM, A7, Registered Nurse (RN), indicated there was no documentation the lead aprons were checked for cracks and flaws in the lead lining. 5. In interview on 3-10-2021 at 1:42 PM, A1, Administrator-Director, indicated there was no policy/procedure for radiation dose limits for employees and confirmed no one had been reviewing the dosimetry reports quarterly.			