

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001193	X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	X3) DATE SURVEY COMPLETED 09/29/2021
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NAME OF PROVIDER OR SUPPLIER MICHIANA SURGERY CENTER LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 3212 HICKORY ROAD, SUITE A MISHAWAKA, IN 46545
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Q 0000 Bldg. 00	This visit was for a Re-certification survey.  Facility Number: 013086  Dates Of Survey: 9/27/2021 to 9/29/2021 and 10/20/2021  QA: 10/04/2021 and 10/28/2021	Q 0000		
Q 0084 Bldg. 00	416.43(e) GOVERNING BODY RESPONSIBILITIES The governing body must ensure that the QAPI program- (1) Is defined, implemented, and maintained by the ASC. (2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness. (3) Specifies data collection methods, frequency, and details. (4) Clearly establishes its expectations for safety. (5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program. Based on document review and interview, the ASC's (Ambulatory Surgery Center) governing body failed to ensure that the QAPI (Quality Assurance Performance Improvement) program is maintained by the ASC; for review of quality assurance program, for 2 quarters (3rd & 4th quarters 2020), and failed to ensure 2 contracted services reviewed for effectiveness in QAPI program (Laboratory & Laundry).	O 0084	Governing body Meetings will be held quarterly starting November 12, 2021 They will be evidenced by meeting agenda, meeting minutes attendance signatures of attendees.  The QAPI meetings will be held	11/19/2021

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 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 disclosed 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.

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	<p>Findings include:</p> <ol style="list-style-type: none"> <li>Review of Medical Staff &amp; Governing Body Board meeting minutes for the last 4 quarters, indicated the following: Lacked meetings for 3rd &amp; 4th quarters 2020.</li> <li>Review of ASC policy titled: "POLICY FOR QUALITY INDICATORS", policy # MSC.6.2, indicated on page 1, under PURPOSE, 2nd sentence, "The data collected on the following quality indicators will be used to: Monitor the effectiveness and safety of the surgical center services", and "The following quality indicators will be monitored:", included point 5 for Lab (laboratory) and point 6 for Laundry/Linen; on page 2, "Must be addressed at each quarterly Quality Council meeting". Effective 10/2013.</li> <li>Review of ASC's QAPI (Quality Assurance Performance Improvement) meeting minutes, indicated the following: <ol style="list-style-type: none"> <li>QAPI meeting on 4/28/2021, lacked entries/documentation for data/quality indicators for Lab and Laundry services.</li> <li>QAPI meeting on 7/8/2021, lacked entries/documentation for data/quality indicators for Lab and Laundry services.</li> <li>Lacked QAPI meeting minutes for 4 quarters of 2020, and 1st quarter 2021.</li> </ol> </li> <li>In interview on 9/28/2021 at approximately 12:00 pm, with ASC administrative staff member A # 2 (Administrator), the following was confirmed: <ol style="list-style-type: none"> <li>That these are the only meeting minutes that could be found.</li> <li>Not sure if there were additional meetings held in 2020, and what previous staff did with the meeting minutes.</li> </ol> </li> </ol>		<p>monthly and the documentation will be provided to the Governing board for review during the quarterly meeting.</p> <p>Linen and Laboratory was addressed in the most recent QAPI meeting and will be going forward as after contacting the Laundry service MSC will be receiving quality documentation.</p> <p>The scheduling of the QAPI will be at the discretion of the Admin. The required staff will be:</p> <p>OR- RN Infection Control Rad Tech Sterile Processing/purchasing The responsible person will be the Admin.</p>		

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Q 0100 Bldg. 00	<p>5. In interview on 9/29/2021 at approximately 11:50 am, with ASC administrative staff member A # 2 (Administrator), confirmed the following:</p> <p>A. These are the QAPI meeting minutes that could be found.</p> <p>B. Lab and Laundry not in meeting minutes.</p> <p>6. No other documentation was provided prior to exit.</p> <p>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.</p> <p>Based on record review, observation, and interview: the facility failed to ensure 1 of 1 fire alarm systems was maintained in accordance with 9.6.1.3. LSC 9.6.1.3 requires a fire alarm system to be installed, tested, and maintained (see tag K345), it could not be assured all facility fire alarm system initiating devices were functional tested annually. LSC 9.6.1.3 requires a fire alarm system to be installed, tested, and maintained (see tag K345), failed to maintain 1 of 1 fire alarm systems in accordance with NFPA 72 (see tag K345), failed to provide written documentation or other evidence the sprinkler system components had been inspected and tested for 1 of 4 quarters (see tag K353), failed to ensure the minimum supply of spare sprinklers was maintained on the premises (see tag K353), the facility failed to ensure 1 of 1 automatic sprinkler piping systems was examined for internal obstructions where conditions exist that could cause obstructed piping as required by NFPA 25 (see tag K353), failed to provide signage for the facility's sprinkler system in accordance with NFPA 25 (see tag K353), failed to ensure 1 of</p>	O 0100	<p>1. LSC 9.6.1.3 requires a fire alarm system to be installed, tested, and maintained in accordance with NFPA 70, National Electrical Code and NFPA 72, National Fire Alarm and Signaling Code. NFPA 72, 2010 Edition, Section 14.2.1.2.1 states the requirements of Section 10.19 shall be applicable when a system is impaired. Section 14.2.1.2.2 states system defects and malfunctions shall be corrected. Inspection of alarm system has been inspected and the upgrade to 5G has been implemented.</p> <p>To prevent from occurring in future the correspondence from Fire company will be reviewed closely.</p>	10/22/2021

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	<p>1 ceiling smoke barriers was maintained to provide at least a one half hour fire resistance rating (see tag K372), failed to provide documentation of a fire drill conducted on the first shift for 1 of 4 quarters (see tag K712), failed to document activation of the fire alarm system for first shift fire drills conducted between 6:00 a.m. and 9:00 p.m. for 3 of 4 quarters (see tag K712), failed to document annual inspection and testing of all fire door assemblies (see tag K761), failed to ensure the vacuum pump room for the facility's piped gas system was maintained with a minimum one-hour fire resistance rating construction (see tag K902).</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to ensure that the location from which it provides services are constructed, arranged and maintained to ensure the provision of quality health care in a safe environment.</p>		<p>Responsible person : Admin. and Safety Officer</p> <p>2. LSC 9.6.1.3 requires a fire alarm system to be installed, tested, and maintained in accordance with NFPA 70, National Electrical Code and NFPA 72, National Fire Alarm and Signaling Code. The fire alarm system initiating devises have been proven functional as evidenced by a fire drill with an alarm pull with Fire Marshall present and verified the signal went through to the firehouse and ADT. To ensure the signal is going through a drill with activation of alarm will be held annually as evidenced by fire drill documentation. Responsible person: Admin. to schedule these drills.</p> <p>3.Duct annual detector inspection was functionally tested by Koorsen and present in the fire safety book and the compliance binder. Inspections will take place semi-annually. Responsible person: Safety Officer and Admin.</p> <p>b. Remote annunciators Will be inspected semi annually by Koorsen. Responsible person: Safety Officer and Admin.</p>		

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			<p>c. &amp; d. Initiating devices (e.g. duct detectors, manual fire alarm boxes, heat detectors, smoke detectors, etc.) d. Notification appliances e. Magnetic hold-open devices</p> <p>An annual duct inspection will be scheduled utilizing a fire safety book. The Safety officer will inform the Admin. when the inspection is due and Admin. will schedule the inspection with Koorsen and Bloofield.</p> <p>Responsible person: Admin. and Safety Officer</p> <p>The fire alarm system has been inspected and documentation is stored onsite.</p> <p>e .All fire doors (29 doors) and assemblies have been checked and have passed inspections. A copy can be found in the compliance binder and the fire safety book.</p> <p>Annual Fire door inspections will be completed as evidenced by documentation. The schedule book of inspections will be utilized to ensure timely inspections are completed.</p> <p>Responsible person: Admin. and Safety Officer</p> <p>*Further inspections will be recorded and kept on site. *All duct DETECTORS have been completed and will be verified and inspected</p>	

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			<p>*Fire alarm system will be maintained and tested per LSC101 and NFPA 72.</p> <p>*The fire alarm was pulled on the 4th quarter fire drill with the Fire Marshall and the signal went to the fire house and ADT as intended.</p> <p>*Fire alarm inspections will be maintained on site</p> <p>*MSC currently have no hold open devices</p> <p>Inspection schedule has been provided to the safety officer in her binder and she will notify the Admin as to when inspections are to be scheduled and the Admin. will make contact and schedule inspections.</p> <p>Responsible person: Admin. and Safety Officer</p> <p>--1 of 1 fire alarm system is maintained in accordance with 9.6.1.3. LSC 9.6.1.3. fire alarm system is installed, tested, and maintained annually. Alarm system has been inspected on 10/22/2021 with a fire alarm system initiating device during fire drill with Fire Marshal. (documentation is on site)</p> <p>Deficiency will be kept from occurring in the future by utilizing the monthly binder developed to ensure compliance of fire alarm inspections. This binder will be reviewed monthly to schedule inspections.</p>	

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			<p>Responsible person: Safety Officer and Admin.</p> <p>Minimum supply of spare sprinklers is now maintained on the premises a total of 6 spare heads). A monthly inspection of the sprinkler room to ensure a quantity of 6 spare heads, wrench and all hanging signs remain in place by the Safety Officer. Responsible person Safety Officer</p> <p>Proper signage for the facility's sprinkler system in accordance with NFPA 25 is present in the sprinkler room. A monthly inspection of the sprinkler room will take place by the Safety Officer to ensure signs are properly placed and are without omission as well as the required number of spare sprinkler heads and wrench. Responsible person: the Safety Officer</p> <p>MSC will ensure ceiling smoke barriers are maintained to provide at least a one half hour fire resistance rating by removing the expandable foam and replace with 3M fire rated red putty Koorsen the fire company has removed the expandable foam and replaced in all penetrations with fire rated 3M putty To ensure compliance any time construction takes place a walk</p>	

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			<p>through with property manager and Admin. will take place to ensure proper materials have been used. Responsible person: Property Manager and Admin.</p> <p>3G/4G communication system has been upgraded to 5G. Communication from the fire company will be coldly monitored as not to overlook necessary upgrade requirements. Responsible person: Admin.</p> <p>---5 year sprinkler test has been performed with no deficiencies. Report is on file on site. Utilizing the safety book will alert the Safety Officer of when to schedule the 5 year inspection. Responsible person: Safety Officer and Admin.</p> <p>---LSC 21.7.1.4 states fire drills in ambulatory health care facilities shall include the transmission of the fire alarm signal and simulation of emergency fire conditions. An unannounced fire drill was performed on 11/3/2021. The Admin. contacted the Fire Marshal and was present for the drill. The alarm system was tested at this time. Fire Marshal ensured the alarm went to the fire station without difficulty. The Fire Marshall documented the drill and timed the event. Documentation is available</p>	

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			<p>on site.</p> <p>The Admin. will continue to schedule education and fire drills quarterly with at least (1) being unannounced and with the Fire Marshall present for activation of the fire alarm.</p> <p>Documentation of the fire drills will be kept on-site.</p> <p>Responsible person: Admin. will be responsible to schedule Fire Drills</p> <p>---NFPA 80 5.2.1 states fire door assemblies shall be inspected and tested not less than annually, and a written record of the inspection shall be signed and kept for inspection by the AHJ. NFPA 80, 5.2.4.1 states fire door assemblies shall be visually inspected from both sides to assess the overall condition of door assembly. NFPA 80, 5.2.4.2 states as a minimum, the following items shall be verified: (1) No open holes or breaks exist in surfaces of either the door or frame.</p> <p>All doors were inspected Responsible person: Admin</p> <p>(2) Glazing, vision light frames, and glazing beads are intact and securely fastened in place, if so equipped.</p> <p>All doors were inspected for defects in glazing and passed. Responsible person: Admin. and Safety Office</p> <p>(3) The door, frame, hinges, hardware, and noncombustible</p>	

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			<p>threshold are secured, aligned, and in working order with no visible signs of damage. Above were all inspected and passed. Responsible person: Admin. and Safety Officer (4) No parts are missing or broken. No parts are missing from doors. Inspection completed and passed. Responsible person: Admin and Safety Officer (5) Door clearances do not exceed clearances listed in 4.8.4 and 6.3.1.7. Door clearances do not exceed standards Inspected and passed. Responsible person: Admin. and Safety Officer (6) The self-closing device is operational; that is, the active door completely closes when operated from the full open position. Inspection completed and passed. Responsible person: Admin. and Safety Officer</p> <p>1.)This inspection will be completed no less than annually, and has recently been completed and documentation is onsite in the fire binder and the compliance binder, each door and assemblies have passed all inspections.</p> <p>The Safety Officer maintains the schedule utilizing the inspection binder and will inform the Admin.</p>	

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			<p>when inspection is due and Admin. will schedule the inspection. Person responsible: Safety Officer and Admin.</p> <p>2.)Glazing inspection will be completed no less than annually, and has recently been completed and documentation is onsite in the fire binder and the compliance binder, each door and assemblies have passed all inspections.</p> <p>The Safety Officer maintains the schedule utilizing the inspection binder and will inform the Admin. when inspection is due and Admin. will schedule the inspection. Person responsible: Safety Officer and Admin.</p> <p>3.)No parts are missing or broken inspection will be completed no less than annually, and has recently been completed and documentation is onsite in the fire binder and the compliance binder, each door and assemblies have passed all inspections.</p> <p>The Safety Officer maintains the schedule utilizing the inspection binder and will inform the Admin. when inspection is due and Admin. will schedule the inspection. Person responsible: Safety Officer and Admin.</p> <p>4.)No parts are missing or broken inspection will be</p>	

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			<p>completed no less than annually, and has recently been completed and documentation is onsite in the fire binder and the compliance binder, each door and assemblies have passed all inspections.</p> <p>The Safety Officer maintains the schedule utilizing the inspection binder and will inform the Admin. when inspection is due and Admin. will schedule the inspection. Person responsible: Safety Officer and Admin.</p> <p>5.)Door clearances do not exceed clearances listed in 4.8.4 and 6.3.1.7 inspection will be completed no less than annually, and has recently been completed and documentation is onsite in the fire binder and the compliance binder, each door and assemblies have passed all inspections.</p> <p>The Safety Officer maintains the schedule utilizing the inspection binder and will inform the Admin. when inspection is due and Admin. will schedule the inspection. Person responsible: Safety Officer and Admin.</p> <p>6.) Self closing device is operational and closes completely when operated from the full open position inspection will be completed no less than annually, and has recently been completed and documentation is onsite in the</p>	

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			<p>fire binder and the compliance binder, each door and assemblies have passed all inspections.</p> <p>The Safety Officer maintains the schedule utilizing the inspection binder and will inform the Admin. when inspection is due and Admin. will schedule the inspection. Person responsible: Safety Officer and Admin.</p> <p>7.) No coordinator is installed at Michiana Surgery Center 8.) Latching hardware operates and secures the door when it is in closed position and inspection will be completed no less than annually, and has recently been completed and documentation is onsite in the fire binder and the compliance binder, each door and assemblies have passed all inspections. The Safety Officer maintains the schedule utilizing the inspection binder and will inform the Admin. when inspection is due and Admin. will schedule the inspection. Person responsible: Safety Officer and Admin.</p> <p>9.)Auxiliary hardware inspection will be completed no less than annually, and has recently been completed and documentation is onsite in the fire binder and the compliance binder, each door and assemblies have passed all</p>	

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			<p>inspections.</p> <p>The Safety Officer maintains the schedule utilizing the inspection binder and will inform the Admin. when inspection is due and Admin. will schedule the inspection. Responsible person: Admin and Safety Officer</p> <p>10.) No field modifications have been made to the door assembly that may void the label the inspection will be completed no less than annually, and has recently been completed and documentation is onsite in the fire binder and the compliance binder, each door and assemblies have passed all inspections.</p> <p>The Safety Officer maintains the schedule utilizing the inspection binder and will inform the Admin. when inspection is due and Admin. will schedule the inspection. Person responsible: Safety Officer and Admin</p> <p>11.) Gasketing and edge seals where required are inspected to verify their presence and integrity the inspection will be completed no less than annually, and has recently been completed and documentation is onsite in the fire binder and the compliance binder, each door and assemblies have passed all inspections.</p>	

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			<p>The Safety Officer maintains the schedule utilizing the inspection binder and will inform the Admin. when inspection is due and Admin. will schedule the inspection.</p> <p>Person responsible: Safety Officer and Admin.</p> <p>---3M rated fire putty has replaced the foam in all firestop ceiling penetrations in the vacuum pump room above the automatic transfer switch and above the entrance door to the room for electrical conduits. 3M fire putty has also replaced and is used at the firestop penetrations of the back wall of the room behind the furnaces. All areas mentioned were scraped free from the foam and replaced with the fire rated 3M product. The SDS information can be reviewed in the compliance book on site.</p> <p>Any future construction the 3M fire putty will be utilized. A walk through will occur during and after any construction with the Admin. and the Property Manager.</p> <p>Responsible person: Admin. and Property Manager</p>	

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Q 0101  Bldg. 00	<p>416.44(a)(1) PHYSICAL ENVIRONMENT</p> <p>The ASC must provide a functional and sanitary environment for the provision of surgical services.</p> <p>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.</p> <p>1. Based on record review, observation, and interview; the facility failed to provide written documentation or other evidence the sprinkler system components had been inspected and tested for 1 of 4 quarters. LSC 4.6.12.1 requires any device, equipment or system required for compliance with this Code be maintained in accordance with applicable NFPA requirements. Sprinkler systems shall be properly maintained in accordance with NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems. NFPA 25, 2011 Edition, Section 4.3.1 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. Section 4.3.2 requires that records shall indicate the procedure performed (e.g., inspection, test, or maintenance), the organization that performed the work, the results, and the date. NFPA 25, Section 5.2.5 requires that waterflow alarm devices shall be inspected quarterly to verify they are free of physical damage. NFPA 25, Section 5.3.3.1 requires the mechanical waterflow alarm devices including, but not limited to, water motor gongs, shall be tested quarterly. Section 5.3.3.2 requires vane-type and pressure switch-type waterflow alarm devices shall be tested semiannually. This</p>	Q 0101	<p>Alarm system has been inspected( 10/22/2021) and documentation is on site.</p> <p>Minimum of spare sprinkler heads are in the sprinkler room (total of 6).</p> <p>Sprinkler system will be checked quarterly and documented in the safety/fire binder. The Safety Officer will inspect the sprinkler room for signage, spare sprinkler heads (6 spare) and wrench this will be managed by the safety officer.</p> <p>Responsible person: Safety Officer</p> <p>3M rated fire putty has replaced the foam in all firestop ceiling penetrations in the vacuum pump room above the automatic transfer switch and above the entrance door to the room for electrical conduits. 3M fire putty has also replaced and is used at the firestop penetrations of the back wall of the room behind the furnaces. All areas mentioned</p>	11/19/2021	

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	<p>deficient practice could affect all patients, staff, and visitors in the facility.</p> <p>Findings include:</p> <p>Based on review of the sprinkler system inspection contractor's "Sprinkler System Inspection" documentation dated 05/18/21 and 10/05/21 with the Clinical Manager during record review from 10:25 a.m. to 2:30 p.m. on 10/20/21, quarterly sprinkler system inspection documentation for the third quarter (July, August, September) 2021 was not available for review. In addition, it had been 140 days in between the two most recent documented sprinkler system inspections in the second quarter (April, May, June) 2021 and the fourth quarter (October, November, December) 2021. Based on interview at the time of record review, the Clinical Manager stated the facility had not been closed due to the Covid-19 pandemic at any point on or after March 2020 and stated quarterly sprinkler system inspection documentation for the third quarter 2021 was not available for review. Based on observations with the Clinical Manager during a tour of the facility from 2:30 p.m. to 4:00 p.m. on 10/20/21, the sprinkler system inspection contractor had affixed hanging tags to the sprinkler system riser for which documentation of waterflow alarm inspection for the third quarter of 2021 was not available for review.</p> <p>This finding was reviewed with the Clinical Manager during the exit conference.</p> <p>2. Based on observation and interview, the facility failed to ensure the minimum supply of spare sprinklers was maintained on the premises. NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection</p>		<p>were scraped free from the foam and replaced with the fire rated 3M product. The SDS information can be reviewed in the compliance book on site.</p> <p>Any future construction the 3M fire putty will be utilized. A walk through will occur during and after any construction with the Admin. and the Property Manager.</p> <p>Responsible person: Admin. and Property Manager</p> <p>Our fire company now has MSC on a schedule for inspections and a monthly binder has been established for Safety Officer to easily keep track of inspections and the timing of them.</p> <p>5 year sprinkler test was completed on 10/22/2021. This document can be accessed on site at MSC in the fire safety binder as well as the compliance binder.</p> <p>Future reminders to schedule this test will be in the Fire Safety Binder and the Safety Officer will notify the Admin. when the test is required and she will schedule.</p> <p>Responsible person: Safety Officer and Admin.</p> <p>A new sign has been hung on the outstanding control valve as of 10/22/2021.</p> <p>The fire inspection company will be held accountable for missing</p>	

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	<p>Systems, 2011 Edition, Section 5.4.1.4 states a supply of spare sprinklers (never fewer than six) shall be maintained on the premises so that any sprinklers that have operated or been damaged in any way can be promptly replaced. The sprinklers shall correspond to the types and temperature ratings of the sprinklers in the property. The sprinklers shall be kept in a cabinet located where the temperature in which they are subjected will at no time exceed 100 degrees Fahrenheit. Section 5.4.1.6.1 states a special wrench shall be provided and kept in the cabinet to be used in the removal and installation of sprinklers. This deficient practice could affect all patients, staff, and visitors in the facility.</p> <p>Findings include:</p> <p>Based on observations with the Clinical Manager during a tour of the facility from 2:30 p.m. to 4:00 p.m. on 10/20/21, a total of two spare sprinklers were noted in the spare sprinkler cabinet in the riser room. Based on interview at the time of the observations, the Clinical Manager stated additional spare sprinklers have been ordered and agreed the minimum supply of spare sprinklers of the type installed in the facility's suite were not maintained in the spare sprinkler cabinet.</p> <p>This finding was reviewed with the Clinical Manager during the exit conference.</p> <p>3. Based on record review, observation, and interview; the facility failed to ensure 1 of 1 automatic sprinkler piping systems was examined for internal obstructions where conditions exist that could cause obstructed piping as required by NFPA 25, 2011 Edition, the Standards for the Inspection, Testing and Maintenance of Water-Based Fire Protection Systems, section</p>		<p>signs and sprinkler heads. The Admin will do an inspection upon their departure after any work is performed to ensure everything is accounted for.</p> <p>Responsible person is Admin.</p>	

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	<p>14.2.2. This deficient practice affects all patients, staff, and visitors.</p> <p>Findings include:</p> <p>Based on review of the sprinkler system inspection contractor's "Inspection &amp; Test Report" documentation dated 02/05/18 with the Clinical Manager during record review from 10:25 a.m. to 2:30 p.m. on 10/20/21, documentation of an internal pipe inspection conducted within the most recent five year period was not available for review. The 02/05/18 inspection documentation stated 5-year due 2018. Review of the sprinkler system inspection contractor's "Inspection &amp; Test Report" documentation dated 08/30/19 also stated "5-year due 2018". Based on interview at the time of record review, the Clinical Manager stated documentation of a current internal pipe inspection was not available for review at the time of the survey. Based on observations with the Clinical Manager during a tour of the facility from 2:30 p.m. to 4:00 p.m. on 10/20/21, the facility has a supervised wet sprinkler system.</p> <p>This finding was reviewed with the Clinical Manager during the exit conference.</p> <p>4. Based on record review, observation and interview; the facility failed to provide signage for the facility's sprinkler system in accordance with NFPA 25. LSC 4.6.12.1 requires any device, equipment or system required for compliance with this Code be maintained in accordance with applicable NFPA requirements. Sprinkler systems shall be properly maintained in accordance with NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems. NFPA 25, 2011 Edition, Section 13.3.1 states each control valve shall be identified and</p>			

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	<p>have a sign indicating the system or portion of the system it controls. This deficient practice could affect all patients, staff, and visitors in the facility.</p> <p>Findings include:</p> <p>Based on review of the sprinkler system inspection contractor's "Inspection &amp; Test Report" documentation dated 02/12/20 with the Clinical Manager during record review from 10:25 a.m. to 2:30 p.m. on 10/20/21, the facility's sprinkler system was missing one control valve sign. The comments section of the 02/12/20 inspection report stated "Missing (1) Control Valve sign". Based on observations with the Clinical Manager during a tour of the facility from 2:30 p.m. to 4:00 p.m. on 10/20/21, the main drain control valve for the facility's sprinkler system was missing its signage. Based on interview at the time of the observations, the Clinical Manager agreed the the main drain control valve for the facility's sprinkler system was missing its signage.</p> <p>This finding was reviewed with the Clinical Manager during the exit conference.</p> <p>5. Based on record review, observation and interview; the facility failed to ensure the vacuum pump room for the facility's piped gas system was maintained with a minimum one-hour fire resistance rating construction. This deficient practice could affect all patients.</p> <p>Findings include:</p> <p>Based on review of facility blueprint documentation with the Clinical Manager during record review from 10:25 a.m. to 2:30 p.m. on 10/20/21, the vacuum pump room for the facility's piped gas system was constructed with</p>			

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Q 0104 Bldg. 00	<p>separation from adjoining spaces with one hour fire resistance rated construction. Based on observations with the Clinical Manager during a tour of the facility from 2:30 p.m. to 4:00 p.m. on 10/20/21, foam was used to firestop ceiling penetrations in the vacuum pump room above the automatic transfer switch and above the entrance door to the room for electrical conduits. Foam was also used to firestop penetrations of the back wall of the room behind the furnaces. Based on interview at the time of the observations, the Clinical Manager did not have documentation stating the UL listing and fire resistance rating of the foam used to firestop the ceiling and wall penetrations in the vacuum pump room.</p> <p>This finding was reviewed with the Clinical Manager during the exit conference.</p> <p>416.44(b)(1)-(3) SAFETY FROM FIRE</p> <p>(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 Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4).</p> <p>(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.</p>			

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	<p>(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.</p> <p>1. Based on record review, observation and interview; the facility failed to ensure 1 of 1 ceiling smoke barriers was maintained to provide at least a one half hour fire resistance rating. LSC 21.3.7.5 refers to Section 8.5. Section 8.5.6.2 states penetrations for cables, conduits, pipes and similar items that pass through a wall constructed as a smoke barrier floor/ceiling assembly shall be protected by a system or material capable of resisting the transfer of smoke. Where a smoke barrier is also constructed as a fire barrier, the penetrations shall be protected in accordance with the requirements of Section 8.3.5 to limit the spread of fire for a time period equal to the fire resistance of the assembly and Section 8.5.6. This deficient practice could affect all patients, staff and visitors.</p> <p>Findings include:</p> <p>Based on review of facility blueprint documentation with the Clinical Manager during record review from 10:25 a.m. to 2:30 p.m. on 10/20/21, the vacuum pump room for the facility's piped gas system was constructed with separation from adjoining spaces with one hour fire resistance rated construction. Based on observations with the Clinical Manager during a tour of the facility from 2:30 p.m. to 4:00 p.m. on 10/20/21, foam was used to firestop ceiling penetrations in the vacuum pump room above the automatic transfer switch and above the entrance door to the room for electrical conduits. Based on interview at the time of the observations, the</p>	Q 0104	<p>Expandable caulk has been removed and 3M fire barrier sealant IC 15Wb+ has been installed in multiple areas of penetration.</p> <p>Admin. and Property manager have done a walk through to ensure no areas were omitted. In the future if construction is performed the Fire putty will be used and the Admin. and Property manager will do a walk through to ensure areas were properly sealed with approved putty.</p> <p>A copy of the work order and the product SDS is on site at Michiana Surgery Center for reference.</p> <p>Responsible person is Admin.</p> <p>--- LSC 9.6.1.3 requires a fire alarm system to be installed, tested, and maintained in accordance with NFPA 70, National Electrical Code and NFPA 72, National Fire Alarm and Signaling Code.</p> <p>The fire alarm system initiating devises have been proven functional as evidenced by a fire drill with an alarm pull with Fire Marshall present and verified the signal went through to the</p>	11/19/2021	

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	<p>Clinical Manager did not have documentation stating the UL listing and the fire resistance rating of the foam used to firestop the ceiling penetrations.</p> <p>This finding was reviewed with the Clinical Manager during the exit conference.</p> <p>2. Based on record review and interview, the facility failed to provide documentation of a fire drill conducted on the first shift for 1 of 4 quarters. This deficient practice affects all patients, staff and visitors.</p> <p>Findings include:</p> <p>Based on review of "Fire Drill Evaluation Form" documentation with the Clinical Manager during record review from 10:25 a.m. to 2:30 p.m. on 10/20/21, documentation of a fire drill conducted on the first shift in the fourth quarter (October, November, December) 2020 was not available for review. Based on interview at the time of record review, the Clinical Manager stated the facility operates one shift per day and agreed documentation of a fire drill conducted on the first shift in the fourth quarter of 2020 was not available for review.</p> <p>This finding was reviewed with the Clinical Manager during the exit conference.</p> <p>3. Based on record review and interview, the facility failed to document activation of the fire alarm system for first shift fire drills conducted between 6:00 a.m. and 9:00 p.m. for 3 of 4 quarters. LSC 21.7.1.4 states fire drills in ambulatory health care facilities shall include the transmission of the fire alarm signal and simulation of emergency fire conditions. This deficient practice could affect all</p>		<p>firehouse and ADT.</p> <p>To ensure the signal is going through a drill with activation of alarm will be held annually as evidenced by fire drill documentation.</p> <p>Responsible person: Admin. to schedule these drills.</p> <p>--Fire drills will be held quarterly on site, with at least (1) being unannounced with the activation of the fire alarm system, with the Fire Marshal present.</p> <p>Documentation will be kept on site.</p> <p>Fire drills will be schedule by the Admin. quarterly</p> <p>Responsible person: Admin.</p>	

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Q 0108 Bldg. 00	<p>patients, staff and visitors in the facility.</p> <p>Findings include:</p> <p>Based on review of "Fire Drill Evaluation Form" documentation with the Clinical Manager during record review from 10:25 a.m. to 2:30 p.m. on 10/20/21, first shift fire drills conducted on 01/11/21, 05/11/21 and on 09/30/21 were conducted at, respectively, 11:30 a.m., 1:04 p.m. and 3:48 p.m. Documentation for each fire drill did not include activation of the fire alarm system and transmission of the fire alarm signal. Based on interview at the time of record review, the Clinical Manager stated the facility operates one shift per day and agreed documentation of the activation of the fire alarm system and transmission of the fire alarm signal for the aforementioned three first shift fire drills was not available for review.</p> <p>This finding was reviewed with the Clinical Manager during the exit conference.</p> <p>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).</p> <p>(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an ASC.</p> <p>(2) If application of the Health Care Facilities Code required under paragraph (c) of this</p>			

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	<p>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.</p> <p>1. Based on record review and interview, the facility failed to ensure 1 of 1 fire alarm systems was maintained in accordance with 9.6.1.3. LSC 9.6.1.3 requires a fire alarm system to be installed, tested, and maintained in accordance with NFPA 70, National Electrical Code and NFPA 72, National Fire Alarm and Signaling Code. NFPA 72, 2010 Edition, Section 14.2.1.2.1 states the requirements of Section 10.19 shall be applicable when a system is impaired. Section 14.2.1.2.2 states system defects and malfunctions shall be corrected. This deficient practice could affect all patients, staff, and visitors.</p> <p>Findings include:</p> <p>Based on review of the fire alarm system inspection contractor's "Important Notice" documentation dated 12/09/19 with the Clinical Manager during record review from 10:25 a.m. to 2:30 p.m. on 10/20/21, the facility's fire and security system's communication system is in need of an upgrade. The 12/09/19 documentation stated "your current fire and/or security system utilizes a 3G/4G cellular communicator to transmit messages to and from the Koorsen monitoring center. When your community is upgraded to LTE cell towers, the communicator in your system will no longer be able to communicate with the Koorsen monitoring center, leaving you and your property at risk. In order to maintain a secure, reliable connection between your fire and/or security system and the Koorsen monitoring center, your system MUST be updated! If your</p>	Q 0108	<p>The supplies for the 3G/4G upgrade have been invoiced and is on the schedule for installation.</p> <p>To prevent from occurring in future the correspondence from Fire company will be reviewed closely. Responsible person : Admin. and Safety Officer</p> <p>The fire alarm system initiating devises have been proven functional as evidenced by a fire drill with an alarm pull on 11/3/2021 with Fire Marshall present and verified the signal went through to the firehouse and ADT.</p> <p>To ensure the signal is going through a drill with activation of alarm will be held annually as evidenced by fire drill documentation. Responsible person: Admin. to schedule these drills.</p> <p>Duct annual detector inspection was functionally tested on: 10/22/2021 by Koorsen and present in the fire safety book and the compliance binder An annual duct inspection will be</p>	11/29/2021

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NAME OF PROVIDER OR SUPPLIER  MICHIANA SURGERY CENTER LLC	STREET ADDRESS, CITY, STATE, ZIP COD 3212 HICKORY ROAD, SUITE A MISHAWAKA, IN 46545
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	<p>system is not updated, you will lose connection to the Koorsen monitoring center". Review of the fire alarm system inspection contractor's "Repair Service Ticket- Description of work" documentation dated 04/07/21 stated "advised customer they will have to upgrade their communication panel due to the 3G/4G service shut off within the next 10-12 months". Based on interview at the time of record review, the Clinical Manager stated she was not aware if the communication system has been upgraded or has been scheduled to be updated.</p> <p>These findings were reviewed with the Clinical Manager during the exit conference.</p> <p>2. Based on record review and interview, it could not be assured all facility fire alarm system initiating devices were functional tested annually. LSC 9.6.1.3 requires a fire alarm system to be installed, tested, and maintained in accordance with NFPA 70, National Electrical Code and NFPA 72, National Fire Alarm and Signaling Code. NFPA 72, 2010 Edition, Section 14.4.5 states unless otherwise permitted by other sections of this code, testing shall be performed in accordance with the schedules in Table 14.4.5, or more often if required by the authority having jurisdiction. Table 14.4.5 Testing Frequencies states initiating devices shall be functional tested annually. This deficient practice could affect all patients, staff, and visitors.</p> <p>Findings include:</p> <p>Based on review of the fire alarm system inspection contractor's "Element of Performance 3" documentation dated 08/13/19 and 08/18/20 with the Clinical Manager during record review from 10:25 a.m. to 2:30 p.m. on 10/20/21, the results</p>		<p>scheduled utilizing a fire safety book. The Safety officer will inform the Admin. when the inspection is due and Admin. will schedule the inspection.</p> <p>Responsible person: Admin. and Safety Officer</p> <p>The fire alarm system has been inspected and documentation</p> <p>All fire doors (29 doors) and assemblies have been checked and have passed inspections. A copy can be found in the compliance binder and the fire safety book.</p> <p>Annual Fire door inspections will be completed as evidenced by documentation. The schedule book of inspections will be utilized to ensure timely inspections are completed.</p> <p>Responsible person: Admin. and Safety Officer</p> <p>Responsible person will be the Admin. to ensure doors and duct detectors are inspected and tested appropriately</p>	

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	<p>of functional testing for 2 of 2 duct detectors in the facility were documented as "Visual" and listed as "Inaccessible" in the "Comments" section of the two reports. In addition, the result of functional testing 2 of 2 duct detectors in the facility listed on "Device Inspection Report" documentation dated 10/05/21 stated "visual only". Based on interview at the time of record review, the Clinical Manager stated additional fire alarm inspection and testing documentation within the most recent twelve month period was not available for review and agreed it could not be assured the facility's two duct detectors had been functional tested within the most recent twelve month period.</p> <p>This finding was reviewed with the Clinical Manager during the exit conference.</p> <p>3. Based on record review and interview, the facility failed to maintain 1 of 1 fire alarm systems in accordance with NFPA 72, as required by LSC 101 Section 9.6. NFPA 72, Section 14.3.1 states that unless otherwise permitted by 14.3.2, visual inspections shall be performed in accordance with the schedules in Table 14.3.1, or more often if required by the authority having jurisdiction. Table 14.3.1 states that the following must be visually inspected semi-annually:</p> <ul style="list-style-type: none"> <li>a. Control unit trouble signals</li> <li>b. Remote annunciators</li> <li>c. Initiating devices (e.g. duct detectors, manual fire alarm boxes, heat detectors, smoke detectors, etc.)</li> <li>d. Notification appliances</li> <li>e. Magnetic hold-open devices</li> </ul> <p>This deficient practice could affect all clients and staff.</p> <p>Findings include:</p>			

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	<p>Based on review of the fire alarm system inspection contractor's "Element of Performance 3" documentation dated 08/18/20 and "Device Inspection Report" documentation dated 10/05/21 with the Clinical Manager during record review from 10:25 a.m. to 2:30 p.m. on 10/20/21, documentation of a visual semi-annual fire alarm system inspection six months after 08/18/20 was not available for review. Based on interview at the time of record review, the Clinical Manager stated the facility had not been closed due to the Covid-19 pandemic at any point on or after March 2020 and agreed documentation for a semi-annual visual fire alarm system inspection six months after 08/18/20 was not available for review at the time of the survey.</p> <p>This finding was reviewed with the Clinical Manager during the exit conference.</p> <p>4. Based on record review, observation, and interview; the facility failed to document annual inspection and testing of all fire door assemblies. LSC 21.7.6 Maintenance and Testing states See 4.6.12. LSC 4.6.12 states whenever or wherever any device, equipment, system, condition, arrangement, level of protection, fire-resistive construction, or any other feature is required for compliance with the provisions of this Code, such device, equipment, system, condition, arrangement, level of protection, fire-resistive construction, or other feature shall thereafter be continuously maintained. Maintenance shall be provided in accordance with applicable NFPA requirements or requirements developed as part of a performance-based design, or as directed by the authority having jurisdiction. LSC 8.3.3.1 states openings required to have a fire protection rating by Table 8.3.4.2 shall be protected by approved,</p>			

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

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	<p>listed, labeled fire door assemblies and fire window assemblies and their accompanying hardware, including all frames, closing devices, anchorage, and sills in accordance with the requirements of NFPA 80, Standard for Fire Doors and Other Opening Protectives, except as otherwise specified in this Code. NFPA 80 5.2.1 states fire door assemblies shall be inspected and tested not less than annually, and a written record of the inspection shall be signed and kept for inspection by the AHJ. NFPA 80, 5.2.4.1 states fire door assemblies shall be visually inspected from both sides to assess the overall condition of door assembly.</p> <p>NFPA 80, 5.2.4.2 states as a minimum, the following items shall be verified:</p> <ol style="list-style-type: none"> <li>(1) No open holes or breaks exist in surfaces of either the door or frame.</li> <li>(2) Glazing, vision light frames, and glazing beads are intact and securely fastened in place, if so equipped.</li> <li>(3) The door, frame, hinges, hardware, and noncombustible threshold are secured, aligned, and in working order with no visible signs of damage.</li> <li>(4) No parts are missing or broken.</li> <li>(5) Door clearances do not exceed clearances listed in 4.8.4 and 6.3.1.7.</li> <li>(6) The self-closing device is operational; that is, the active door completely closes when operated from the full open position.</li> <li>(7) If a coordinator is installed, the inactive leaf closes before the active leaf.</li> <li>(8) Latching hardware operates and secures the door when it is in the closed position.</li> <li>(9) Auxiliary hardware items that interfere or prohibit operation are not installed on the door or frame.</li> <li>(10) No field modifications to the door assembly</li> </ol>			

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Q 0122 Bldg. 00	<p>have been performed that void the label. (11) Gasketing and edge seals, where required, are inspected to verify their presence and integrity. This deficient practice could affect all patients, staff, and visitors.</p> <p>Findings include:</p> <p>Based on review of the fire door inspection contractor's "Annual Fire/Smoke Door Inspection Checklist" documentation dated December 2018 with the Clinical Manager during record review from 10:25 a.m. to 2:30 p.m. on 10/20/21, documentation for current annual fire door inspections was not available for review. Based on interview at the time of record review, the Clinical Manager stated the most recent documented fire door inspections were in December 2018 and agreed documentation for current annual fire door inspections was not available for review. Based on review of facility blueprint documentation at the time of record review, the corridor wall for the vacuum pump room for the facility's piped gas system was constructed as a one hour fire resistance rated wall. Based on observations with the Clinical Manager during a tour of the facility from 2:30 p.m. to 4:00 p.m. on 10/20/21, a 3-hour fire resistance rating label was affixed to the corridor door to the vacuum pump room.</p> <p>This finding was reviewed with the Clinical Manager during the exit conference.</p> <p>416.45(b) REAPPRAISALS Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as</p>			

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Q 0201  Bldg. 00	<p>appropriate. Based on document review and interview, the ASC's (Ambulatory Surgery Center) failed to ensure performance evaluations for reappointment, for 8 of 9, MD's (Doctor of Medicine) credentialing files reviewed. (MD's # 1, # 2, # 3, # 4, # 5, # 6, # 7 and # 8).</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>Review of "MEDICAL STAFF BYLAWS", indicated a lack of language for Physician performance evaluations for reappointments.</li> <li>Review of 9 MD's credentialing files, indicated that 8 (as above), lacked a performance evaluation.</li> <li>In interview on 9/28/2021 at approximately 2:40 pm, with ASC administrative staff member A # 3 (Credentialing Coordinator), confirmed the following: <ul style="list-style-type: none"> <li>A. No performance evaluations for the MD's credentialing files reviewed.</li> <li>B. Not aware of what is needed on a performance evaluation; for reappointments.</li> </ul> </li> </ol> <p>416.49(a) LABORATORY SERVICES If the ASC performs laboratory services, it must meet the requirements of Part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with Part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of services to</p>	Q 0122	<p>reviews of performance evaluations have been documented and signed at the quarterly Board meeting on 11/12/2021. Each staff will have a minimum of two reviews per quarter depending on the number of patients seen. These reviews will be kept in the physician/ CRNA's personnel files</p> <p>Board meetings will be held quarterly and the reviews will be completed at this time by the CMO. This will be evidenced by review and signature on each document reviewed.</p> <p>The Admin. or chosen staff member will randomly pull providers for review for quarterly board meeting.</p> <p>The responsible person performing the reviews will be the Chief Medical officer.</p>	11/19/2021	

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Q 0233 Bldg. 00	<p>perform the referral test in accordance with the requirements of Part 493 of this chapter. Based on document review and interview, the ASC (Ambulatory Surgery Center) failed to provide a contract or an agreement, for the reference laboratory (RL # 20) utilized for pathology and medical laboratory services.</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>Review of the contract binder, for contracts and agreement/arrangements; lacked documents for RL # 20 utilized; where surgical specimens are sent to for interpretation &amp; diagnostics.</li> <li>In interview on 9/29/2021 at approximately 11:45 am, with A # 2 (Administrator), confirmed the following:               <ol style="list-style-type: none"> <li>That specimens are sent out to RL # 20, from surgical cases; specimens obtained by the Physician.</li> <li>Not aware of a contract, agreement/arrangement, or anything in writing for this service, provided by RL # 20, and does not recall there ever being one.</li> </ol> </li> </ol> <p>416.50(f)(3) SAFETY - ABUSE/HARASSMENT [The patient has the right to - ] (3) Be free from all forms of abuse or harassment</p> <p>Based on document review and interview, the facility failed to provide new employees, during their orientation program, patient abuse/neglect training in two (2) instances (A # 2 &amp; PS # 4) and failed to provide annual abuse/neglect training in one (1) instance (A # 2).</p> <p>Findings include:</p>	Q 0201	<p>The Admin. Contacted the South Bend Med Foundation where Michiana Surgery Center sends their specimens to obtain a contract.</p> <p>A contract was provided with appropriate signatures and details</p> <p>The contract resides in the contract binder</p> <p>Any time Michiana Surgery Center engages in work outside the facility a contract will be requested and will reside in the contract binder.</p> <p>Responsible person is the Admin.</p>	11/19/2021
	<p>Based on document review and interview, the facility failed to provide new employees, during their orientation program, patient abuse/neglect training in two (2) instances (A # 2 &amp; PS # 4) and failed to provide annual abuse/neglect training in one (1) instance (A # 2).</p> <p>Findings include:</p>	O 0233	<p>Per MSC policy MSC.3.04 staff will upon hire and annually be provided education on Elder Abuse and Neglect.</p> <p>This education will be kept in the staff competency and education binder.</p>	11/19/2021

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S 0000  Bldg. 00	<p>1. The facility policy titled, "ABUSE: DEFINED CRITERIA, ASSESSMENT AND REPORTING", policy # MSC.3.04, indicated in-service for staff to identify possible victims of abuse will be given on a yearly basis. It was the policy of the facility to protect patients from real or perceived abuse, neglect or exploitation from anyone, including staff members, students, volunteers, other patients, visitors or family members. This policy was reviewed on 07/01/2019.</p> <p>2. Review of the personnel file for A # 2 (Administrator), indicated the orientation packet lacked abuse/neglect training and his/her file lacked annual abuse/neglect training.</p> <p>3. Review of the personnel file for PS # 4 (Scribe), indicated the orientation packet lacked annual patient abuse/neglect training.</p> <p>4. In interview on 09/29/2021 at approximately 11:00 am with A # 2 and PS # 4, confirmed they had not had abuse/neglect training during orientation and A # 2 had not completed his/her annual abuse/neglect training.</p> <p>This visit was for a State licensure survey.</p> <p>Facility Number: 013086</p> <p>Dates Of Survey: 9/27/2021 to 9/29/2021</p> <p>QA: 10/04/2021</p>	S 0000	<p>Education is provided by NCEA (National Center on Elder Abuse).</p> <p>The admin. will be responsible for staff to engage in this education as evidenced of taking the required quiz following the review of information on a yearly basis.</p>	

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S 0106  Bldg. 00	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (a)(3)</p> <p>The governing body shall do the following:</p> <p>(3) Review the bylaws at least triennially. Based on document review and interview, the ASC's (Ambulatory Surgery Center) governing body failed to ensure that the Bylaws were reviewed at least triennially; and failed to follow ASC's Governing Body Bylaws for review of Bylaws annually.</p> <p>Findings include:</p> <p>1. Review of the Governing Body Bylaws, indicated the following: A. Last approved date of 12/13/2013. B. On page 3, under Section IV., "the Governing Body shall address the following issues annually"; point 13, "Review Governing Body Bylaws".</p> <p>2. In interview on 9/29/2021 at approximately 12:20 pm, with administrative ASC staff member A # 1 (Materials Manager), the following was confirmed: A. That these were the Governing Body Bylaws that were found/located. B. Not aware of; if or when the Governing Body Bylaws were last reviewed and approved by the Board.</p>	S 0106	<p>The Governing Body has met and reviewed the Governing bylaws and Medical Staff Bylaws and have signed and updated as necessary. Bylaws will be kept in binder in the designated area for reference.</p> <p>The Governing body will meet and review the Governing Body Bylaws annually and Medical Staff Bylaws triennially in conjunction with a quarterly board meeting.</p> <p>The Admin will ensure that this review will be on the Governing Body Board Meeting agenda for an annual review and triennial review respectfully.</p> <p>Deficiency has been completed- 11/12/2021</p> <p>Responsible person: Admin.</p>	11/12/2021	
S 0110  Bldg. 00	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES</p>				

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410	<p>IAC 15-2.4-1 (a)(5)</p> <p>The governing body shall do the following:</p> <p>(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.</p> <p>Based on document review and interview, the ASC's (Ambulatory Surgery Center) governing body failed to ensure review of quality assessment program at least quarterly, for 2 quarters. (3rd &amp; 4th quarters 2020).</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>Review of Medical Staff &amp; Governing Body Board meeting minutes for the last 4 quarters, indicated; lacked meetings for 3rd &amp; 4th quarters 2020.</li> <li>In interview on 9/28/2021 at approximately 12:00 pm, with ASC administrative staff member A # 2 (Administrator), the following was confirmed:               <ol style="list-style-type: none"> <li>That these are the only meeting minutes that could be found.</li> <li>Not sure if there were additional meetings held in 2020, and what previous staff did with the meeting minutes.</li> </ol> </li> <li>No other documentation was provided prior to exit.</li> </ol>	S 0110	<p>Medical Staff and Governing Body are one in the same currently</p> <p>This governing Body has met on November 12, 2021 and reviewed the quality reports for the 3rd quarter and the quality assessment program will be reviewed at least quarterly in future meetings.</p> <p>Scheduled Medical Staff and Governing Body meetings are scheduled for: November 12/2021 April 8, 2022 July 15, 2022 October 14, 2022</p> <p>These meetings will be evidenced by: __ Meeting agenda --- Meeting minutes --- Signature log of attendees Meetings will be held in person at Michiana Surgery Center unless exception is noted</p>	11/12/2021

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S 0122 Bldg. 00	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (b)(3)</p> <p>The governing body shall do the following:</p> <p>(3) Ensure that the medical staff has approved bylaws and rules, and that the bylaws and rules are reviewed and approved at least triennially by the governing body.</p> <p>Based on document review and interview, the ASC's (Ambulatory Surgery Center) failed to ensure that medical staff bylaws and rules are reviewed and approved at least triennially by the governing body.</p> <p>Findings include:</p> <p>1. Review of ASC Medical Staff Bylaws, indicated the following:  A. On page 5, titled at the top of the page; under "MEDICAL STAFF BYLAWS"; noted the name of a different ASC; not the name of this ASC.  B. On the last page, under Section 3. Relationship to Bylaws; for Approved by the Medical Staff" and "Adopted by the Governing Body"; included signatures for each; although lacked a date.</p> <p>2. Review of ASC policy titled: "RULES AND REGULATIONS OF THE MEDICAL STAFF", policy # MSC.9.3, indicated the following:  A. An effective date of 10/1/2013.</p>	S 0122	<p>Admin. will be responsible for scheduling and the agenda for each meeting</p> <p>The Medical Staff now has updated Bylaws with appropriate signatures and dates present. The ASC name has been corrected on this document.</p> <p>This has been addressed at he Medical Staff Board meeting held November 12,2021.</p> <p>The Governing Board will review the medical staff bylaws no less than annually and documentation of such review will be documented within the governing Body Board Meeting Minutes</p> <p>Medical staff will acknowledge acceptance of the bylaws annually by reviewing them as evidenced by signatures.</p> <p>The Admin. is responsible ensure the review will take place during the said meeting.</p>	11/12/2021

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S 0156 Bldg. 00	<p>B. Lacked a review/revised and approved date, within the last 3 years.</p> <p>3. Review of Governing Body Bylaws, lacked language/content for review and approval of Medical Staff Bylaws and Rules &amp; Regulations. Effective 12/2013.</p> <p>4. In interview on 9/29/2021 at approximately 12:50 pm, with ASC administrative staff member A # 2 (Administrator), the following was confirmed:</p> <p>A. That these were the Medical Staff Bylaws and Rules &amp; Regulations that could be found, for the Center.</p> <p>B. Not sure when the last time that they may have been reviewed or approved.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (E)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(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.</p> <p>Based on document review and interview, the facility failed to maintain and complete an annual performance evaluation for five (5) of seven (7) staff members files reviewed (NS # 2, NS # 4, A #</p>	S 0156	ASC Admin. will review all human resources/personnel files no less than annually to ensure that compliance is maintained	11/19/2021

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S 0162  Bldg. 00	<p>1, PS # 2 and NS # 3).</p> <p>Findings include:</p> <p>1. The facility policy titled, "PERFORMANCE EVALUATION", policy # MSC.10.14, indicated all employees of the facility will receive performance evaluations and formal performance reviews on at least an annual basis. This policy was effective on 10/01/2013.</p> <p>2. Review of the Governing Bylaws dated 12/12/2013, indicated the Governing Body shall address evaluations of non-privileged personnel issues annually and shall "require evaluations" of all non-privileged personnel once in a twelve-month period for the purpose of assessing employee performance.</p> <p>3. The personnel files were reviewed on 09/28/2021. The files lacked annual performance evaluations for staff member NS # 2 (Registered Nurse-RN), NS # 4 (RN), A # 1 (Materials Manager), PS # 2 (Radiology/Safety Officer and NS # 3 (RN Infection Control).</p> <p>4. In interview on 09/28/2021 at approximately 2:28 pm with administrative staff member A # 2 (Administrator), confirmed the annual performance evaluations were not completed and/or were missing for the above staff.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (G)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p>		<p>ASC Admin. will ensure that all employees are evaluated on job performance based on job descriptions within the first 90 days of employment and annually upon their anniversary date.</p> <p>The Governing body will quarterly evaluate non-privileged personnel for the purpose of performance during quarterly board meeting as evidenced by documented reviews.</p> <p>Reviews will be completed by November 19,2021</p>		

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S 0164	<p>(G) Ensuring cardiopulmonary resuscitation (CPR) competence in accordance with current standards of practice and center policy for all health care workers including contract and agency personnel, who provide direct patient care.</p> <p>Based on document review and interview, the ASC's (Ambulatory Surgery Center) governing body failed to ensure CPR (Cardiopulmonary resuscitation) competence in accordance with current standards and center policy for all health care workers, who provide patient care, for 4 of 11 credentialing files reviewed. (MD's {Doctor of Medicine} [Pain Management] # 4, # 6, # 7 and # 8).</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. Review of ASC policy titled: "PHYSICIAN AND STAFF REQUIREMENTS FOR CPR TRAINING", policy # MSC.2.45, indicated in first paragraph, "CPR 'competence for all healthcare workers, including agency or contract personnel' shall include physicians as well". Effective date: 10/1/2013.</li> <li>2. Review of credentialing files, indicated files lacked documentation for CPR certification/competence.</li> <li>3. In interview on 9/28/2021 at approximately 3:35 pm, with ASC administrator staff member A # 3 (Credentialing Coordinator), confirmed that MD's # 4, # 6, # 7 and # 8, do not have current CPR certification.</li> </ol> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND</p>	S 0162	<p>ASC Admin. will review and revise CPR policies and procedures and in-service employees and physicians.</p> <p>ASC Admin. will evidence this in-service and update policy</p> <p>All CPR Certifications will be added to the personnel and Credentialing files.</p> <p>When Admin reviews personnel files annually she will ensure all CPR Certificates are up to date.</p> <p>Completion of this deficiency will be November 19,2021.</p>	11/19/2021			

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Bldg. 00	<p><b>DUTIES</b> 410 IAC 15-2.4-1 (c)(5) (H)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(H) A post offer physical examination and employee health monitoring in accordance with the center's infection control program.</p> <p>Based on document review and interview, the facility failed to ensure a post offer physical examination was completed for two (2) of eight (8) staff members reviewed (PS # 1 and NS # 2).</p> <p>Findings include:</p> <p>1. The facility policy titled, "EMPLOYEE PHYSICAL EXAMINATION", policy # MSC.10.17, indicated employees of the facility are required to have an annual physical examination which must be completed within ninety (90) days of hire. Thereafter, the history and physical examination shall be reviewed and updated annually. This policy was effective 10/01/2013.</p> <p>2. The personnel files were reviewed on 09/28/2021. The files lacked a post offer physical examination for staff members NS # 2 (Registered Nurse-RN) and PS # 1 (Certified Scrub Tech-CST).</p> <p>3. In interview on 09/28/2021 at approximately 2:28 pm with administrative staff member A # 2 (Administrator), confirmed the post offer physical examination were not completed and/or were missing for the above staff.</p>	S 0164	<p>Employee Physical examinations Policy (MSC.10.17) will be revised to reflect compliance with regulations and approved by the Governing Board as verified with signatures of acceptance.</p> <p>Personnel files will be updated by November 19, 2021 to contain a post offer physical.</p> <p>This will not be missed again as one Admin will be in charge of the personnel files and will inform new employees of the necessity of such a physical requirement.</p>	11/19/2021	
S 0166	410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND				

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Bldg. 00	<p><b>DUTIES</b> 410 IAC 15-2.4-1 (c)(5) (I)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(I) Requiring all services to have policies and procedures that are updated as needed and reviewed at least triennially.</p> <p>Based on document review and interview, the ASC's (Ambulatory Surgery Center) governing body failed to ensure that all policies and procedures are updated and reviewed at least triennially as per regulation, for 10 service areas (Anesthesia, Patient Rights, PACU {Post anesthesia care unit}, Nursing, Medical Staff, Infection Control, Quality, Medical Records, Laboratory and Environmental Control).</p> <p>Findings include:</p> <p>1. Review of established policy and procedures for all service areas, indicated the following:  A. Lacked a date within the last 3 years for a review, a revision and an approval by the governing body.  B. The effective date on these policies was noted as "1/10/13", for the above 10 noted service areas.</p> <p>2. In interview on 9/28/2021 at approximately 3:15 pm, with A # 1 (Materials Manager), the following was confirmed:  A. These are the policies &amp; procedures that were found.  B. Not aware if policies &amp; procedures have been reviewed and approved in the last 3 years.</p>	S 0166	<p>All Policies and Procedures will be reviewed and revised in accordance with regulations.</p> <p>Policies will be reviewed with the board via sending them via email or during quarterly board meetings. The acceptance and review of the policies are evidenced by signatures of the board members.</p> <p>Moving forward the Governing body will review and acknowledge revisions to policies and procedures.</p> <p>Governing Board will note within the Meeting Minutes that all policies and procedures are reviewed no less than every three years. The Admin. will ensure the policies to be reviewed will be added to the meeting minutes.</p> <p>All policies will be reviewed no later than November 19, 2021.</p>	11/19/2021	

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S 0226 Bldg. 00	<p>3. In interview on 9/27/2021 at approximately 3:45 pm, with A # 2 (Administrator), the following was confirmed:</p> <p>A. Not sure when the last time policies &amp; procedures were reviewed by Medical staff and forwarded to the governing body; can't find where they would have been done.</p> <p>B. Not sure if there were policies &amp; procedures on line for the ASC, that were updated, approved and in the computer by the previous administrative staff. Not able to find updated policies &amp; procedures.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(e)(3)</p> <p>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:</p> <p>(3) Ensure that the center maintains a list of all contracted services, including the scope and nature of the services provided.</p> <p>Based on document review and interview, the ASC's (Ambulatory Surgery Center) governing body failed to ensure that a service delivered to the center was included in list of contracted services, and included scope and nature of services provided. (Laboratory services).</p> <p>Findings include:</p> <p>1. Review of contract binder for services provided to the ASC by contract or by agreement/arrangement; lacked a document for</p>	S 0226	<p>Contract Binder will be updated</p> <p>All contracts will be reviewed no less than quarterly during Governing Body Board meetings to ensure that they remain in place and are accurate.</p> <p>Evidenced of this review will be documented within the Governing Body Board meeting minutes.</p>	11/19/2021

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S 0300 Bldg. 00	<p>the service of lab (laboratory), that is provided by a reference lab (RL # 20), in the county.</p> <p>2. In interview on 9/29/2021 at approximately 11:45 am, with ASC administrative staff member A # 2 (Administrator), the following was confirmed:</p> <p>A. That specimens are sent out to RL # 20, from surgical cases; specimens obtained by the Physician.</p> <p>B. Not aware of a contract, agreement/arrangement, or anything in writing for this service, provided by RL # 20, and does not recall there ever being one.</p> <p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)</p> <p>(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 ASC's (Ambulatory Surgery Center) failed to ensure that services delivered in the center under contract, are part the comprehensive quality assessment program, in which all areas participate, for 2 contracted services. (Laboratory &amp; Laundry).</p>	S 0300	<p>MSC has requested a contract with the Laboratory in which we do business. The contract binder now contains a contract as the Admin. had requested one from the facility.</p> <p>Any outside vendor will be required to provide a contract for services.</p> <p>This Contract has been reviewed and is present. November 19, 2021</p> <p>Responsible person will be the Admin.</p> <p>QAPI Meetings will be held monthly the Second Monday of the month beginning November 10, 2021, these meetings will be scheduled by the Admin.</p> <p>QAPI Meetings will be evidenced</p>	11/12/2021	

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S 0442 Bldg. 00	<p>Findings include:</p> <ol style="list-style-type: none"> <li>Review of ASC policy titled: "POLICY FOR QUALITY INDICATORS", policy # MSC.6.2, indicated on page 1, under PURPOSE, 2nd sentence, "The data collected on the following quality indicators will be used to: Monitor the effectiveness and safety of the surgical center services", and "The following quality indicators will be monitored:", included point 5 for Lab (laboratory) and point 6 for Laundry/Linen; on page 2, "Must be addressed at each quarterly Quality Council meeting". Effective 10/2013.</li> <li>Review of ASC's QAPI (Quality Assurance Performance Improvement) meeting minutes, indicated the following: <ol style="list-style-type: none"> <li>QAPI meeting on 4/28/2021, lacked entries/documentation for data/quality indicators for Lab and Laundry services.</li> <li>QAPI meeting on 7/8/2021, lacked entries/documentation for data/quality indicators for Lab and Laundry services.</li> <li>Lacked QAPI meeting minutes for 4 quarters of 2020, and 1st quarter 2021.</li> </ol> </li> <li>In interview on 9/29/2021 at approximately 11:50 am, with ASC administrative staff member A # 2 (Administrator), confirmed the following: <ol style="list-style-type: none"> <li>These are the QAPI meeting minutes that could be found.</li> <li>Lab and Laundry not in meeting minutes.</li> </ol> </li> </ol> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(viii)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p>		<p>by:</p> <ul style="list-style-type: none"> <li>--Meeting Agenda</li> <li>--Meeting Minutes</li> <li>--Signature Log of attendees</li> </ul> <p>These meetings will be held in person at Michiana Surgery Center unless exception is noted in the minutes.</p> <p>Findings from the meeting will be discussed at the Medical Staff and Governing Board Meetings on a quarterly basis as evidenced by signatures on the QAPI document reviewed.</p> <p>Policy will be updated to show compliance.</p> <p>Policy will be revised and reviewed by the Governing Board and evidenced by Signatures. Laboratory and Laundry services are part of the comprehensive quality assessment program. and are contained in the Contract binder.</p> <p>This information will be completed by November 12,2021. Responsible person is Admin.</p>	
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	<p>(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:</p> <p>(viii) An employee health program to determine the communicable disease history of new personnel as well as an ongoing program for current personnel as required by state and federal agencies.</p> <p>Based on document review and interview, the facility failed to obtain a staff members signature waiving the Hepatitis B vaccine in one instance (A # 1), failed to obtain a staff members vaccination titers in one (1) instance (A # 2) and failed to complete the annual Mantoux (Purified Protein Derivative-PPD) tests in seven (7) instances (PS # 1, NS # 1, NS # 2, NS # 4, A # 1, PS # 2 and NS # 3).</p> <p>Findings include:</p> <p>1. The facility policy titled, "EMPLOYEE VACCINATIONS", policy # MSC.5.52, indicated if Hepatitis B vaccine is waived, documentation must be signed. Rubella, Rubeola and Varicella titers should be drawn within ninety (90) days and PPD's should be completed within thirty (30) days of hire, and annually. There was not a date on the policy.</p> <p>2. Review of the staff members personnel files on 09/28/2021, indicated A # 1's (Materials Manager) personnel file lacked the signed Hepatitis B waiver and annual PPD, A # 2's (Administrator) personnel file lacked his/her vaccination titers and annual PPD, PS # 1's (Certified Scrub Tech-CST)</p>	S 0442	<p>Infection control Policy will be reviewed and revised By the Governing Board and evidenced by the meeting minutes and signatures contained on the policies.</p> <p>Infection Control Committee will meet monthly to ensure policy and procedures remain in compliance.</p> <p>Revised Employee Vaccination Policy (MSC.5.52) per CDC website the State of Indiana does not require ASC's to keep vaccination records. <a href="https://www2.cdc.gov/vaccines/stat evaccsApp/Administration.asp? statetmp=IN">https://www2.cdc.gov/vaccines/stat evaccsApp/Administration.asp? statetmp=IN</a></p> <p>Revision/ Revocation of this policy will be at the guidance of the Governing Board and evidenced by Governing Body Board meeting minutes and signatures of review.</p> <p>PPD test or titer will be performed</p>	11/19/2021

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S 0526 Bldg. 00	<p>personnel file lacked his/her annual PPD, NS # 1's (Registered Nurse-RN) personnel file lacked his/her annual PPD, NS # 2's (RN) personnel file lacked his/her annual PPD, NS # 4's (RN) personnel file lacked his/her annual PPD, PS # 2's (Radiology/Safety Officer) personnel file lacked his/her annual PPD and NS # 3's (RN Infection Control Officer) personnel file lacked his/her annual PPD.</p> <p>3. In interview on 09/28/2021 at approximately 2:28 pm with administrative staff member A # 2, confirmed the documentation was missing from the above staff member's personnel files.</p> <p>410 IAC 15-2.5-2 LABORATORY SERVICES 410 IAC 15-2.5-2 (h)</p> <p>(h) All nursing and other center personnel performing laboratory testing shall have competency assessed annually with documentation of assessment maintained in the employee file for the procedures performed.</p> <p>Based on document review and interview, the facility failed to ensure point of care (POC) training was completed for two (2) of eight (8) staff members (A # 2 &amp; NS # 3).</p> <p>Findings include:</p> <p>1. The facility policy titled, "COMPETENCY ASSESSMENT", policy # MSC.10.3A, indicated competency assessment will occur on an ongoing basis. The continuum will include assessment during the initial competencies, orientation period, and ongoing annual competency assessment. This policy was effective on 10/01/2013.</p>	S 0526	<p>annually, Hep B will be in personnel file or a Declination will be accepted.</p> <p>The compliance with this will be the responsibility of the Admin. upon hire of new staff.</p> <p>Competency Assessment policy (MSC.10.3A) will be revised to show compliance</p> <p>Revision/Revocation of this policy will be at the guidance of the Governing Board and evidenced by the Governing Board signatures on the policy.</p> <p>The annual education and competencies will be reviewed yearly to ensure each staff member that performs Glucose or HCG testing has a competency no</p>	11/19/2021

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S 0704 Bldg. 00	<p>2. Glucometer testing is performed at the facility.</p> <p>2. The personnel files were reviewed on 09/28/2021. The files lacked glucometer POC training documentation for staff members A # 2 (Administrator) and NS # 3 (Registered Nurse-RN/Infection Control Officer).</p> <p>3. In interview on 09/28/2021 at approximately 2:28 pm with administrative staff member A # 2, confirmed glucometer POC training had not been completed and/or was missing from the above staffs personnel file.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(a)(1)</p> <p>The medical staff shall do the following:</p> <p>(1) Conduct outcome-oriented performance evaluations of its member at least biennially.</p> <p>Based on document review and interview, the ASC's (Ambulatory Surgery Center) Medical staff failed to ensure outcome-oriented performance evaluations of its members at least biennially, for 8 of 9, MD's (Doctor of Medicine) credentialing files reviewed. (MD's # 1, # 2, # 3, # 4, # 5, # 6, # 7 and # 8).</p> <p>Findings include:</p> <p>1. Review of "MEDICAL STAFF BYLAWS", indicated a lack of language for Physician performance evaluations at least biennially.</p> <p>2. Review of 9 MD's credentialing files, indicated</p>	S 0704	<p>older than a year in their file.</p> <p>Infection prevention Committee will be responsible to ensure this remains in compliance.</p> <p>Medical Staff Rules will be approved by the Medical staff and Governing Board.</p> <p>Outcome-oriented Performance evaluations will be performed quarterly by the Medical Staff Board as evidenced by a documented record outcome by reviewing the providers chart. These evaluations will be kept in the providers personnel file.</p> <p>The Medical Staff Board will be</p>	11/19/2021

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S 0732 Bldg. 00	<p>that 8 (as above), lacked a performance evaluation.</p> <p>3. In interview on 9/28/2021 at approximately 2:40 pm, with ASC administrative staff member A # 3 (Credentialing Coordinator), confirmed the following:</p> <p>A. No performance evaluations for the MD's credentialing files reviewed.</p> <p>B. Not aware of what is needed on a performance evaluation; for reappointments.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(2)</p> <p>These bylaws and rules must be as follows:</p> <p>(2) Be reviewed at least triennially.</p> <p>Based on document review and interview, the ASC's (Ambulatory Surgery Center) failed to ensure that medical staff bylaws and rules are reviewed and approved at least triennially.</p> <p>Findings include:</p> <p>1. Review of ASC Medical Staff Bylaws, indicated the following:</p> <p>A. On page 5, titled at the top of the page; under "MEDICAL STAFF BYLAWS"; noted the name of a different ASC; not the name of this ASC.</p> <p>B. On the last page, under Section 3. Relationship to Bylaws; for Approved by the Medical Staff" and "Adopted by the Governing Body"; included signatures for each; although lacked a date.</p>	S 0732	<p>responsible to review personnel quarterly.</p> <p>Medical Staff By-laws will be reviewed and approved by the medical staff no less than every three years.</p> <p>Responsibility of the Admin. to add to the board meeting no less than every three years for review.</p> <p>During Medical Staff and Governing Body Board meeting the Medical Staff Bylaws were reviewed and signed</p> <p>The 5th page has been amended to reflect Michiana Surgery Center.</p> <p>The last page under section 3 has</p>	11/19/2021

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S 0736 Bldg. 00	<p>2. Review of ASC policy titled: "RULES AND REGULATIONS OF THE MEDICAL STAFF", policy # MSC.9.3, indicated the following:</p> <p>A. An effective date of 10/1/2013.</p> <p>B. Lacked a review/revised and approved date, within the last 3 years.</p> <p>3. In interview on 9/29/2021 at approximately 12:50 pm, with ASC administrator staff member A # 2 (Administrator), the following was confirmed:</p> <p>A. That these were the Medical Staff Bylaws and Rules &amp; Regulations that could be found, for the Center.</p> <p>B. Not sure when the last time that they may have been reviewed or approved.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(B)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(B) Meeting requirements of the medical staff to include, at a minimum, the following:</p> <p>(i) Frequency, at least quarterly. (ii) Attendance.</p> <p>Based on document review and interview, the ASC's (Ambulatory Surgery Center) Medical Staff failed to ensure quarterly meetings of the Medical Staff. (3rd &amp; 4th quarters 2020).</p> <p>Findings include:</p> <p>1. Review of Medical Staff &amp; Governing Body</p>	S 0736	<p>been updated with current Medical Director's signature and date.</p> <p>Template for the Medical Staff Meetings will be revised to ensure compliance</p> <p>Template will be approved as part of the Medical Staff meeting</p> <p>Acknowledgement of the template</p>	11/19/2021

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S 0930  Bldg. 00	<p>Board meeting minutes for the last 4 quarters, indicated; lacked meetings for 3rd &amp; 4th quarters 2020.</p> <p>2. In interview on 9/28/2021 at approximately 12:00 pm, with ASC administrative staff member A # 2 (Administrator), the following was confirmed:</p> <p>A. That these are the only meeting minutes that could be found.</p> <p>B. Not sure if there were additional meetings held in 2020, and what previous staff did with the meeting minutes.</p> <p>3. No other documentation was provided prior to exit.</p> <p>410 IAC 15-2.5-5 PATIENT CARE SERVICES 410 IAC 15-2.5-5(b)(5)</p> <p>(b) Written patient care policies and procedures shall be available to personnel and shall include, but not be limited to, the following:</p> <p>(5) A provision that all nursing personnel meet annual inservice requirements as established by center and federal and state requirements. Based on document review and interview, the facility failed to ensure annual competencies were completed for six (6) of eight (8) staff members (PS # 1, NS # 4, A # 1, PS # 2, NS # 3 &amp; A # 2) and failed to ensure abuse/neglect training had been completed during orientation for two (2) of eight (8) staff members (A # 2 &amp; PS # 4).</p> <p>Findings include:</p> <p>1. The facility policy titled, "COMPETENCY</p>	S 0930	<p>will be evidenced within the Medical Staff Meeting Minutes utilized on 11/12/2021.</p> <p>Medical Staff Meetings will be held quarterly and the Admin. is responsible for putting the meetings on the physicians calendars and utilizing the document for the meetings.</p> <p>At completion of meetings the minutes will be placed in the Board meeting Binder.</p> <p>Competency and Assessment Policy MSC.10.3A will be revised to show compliance. Revision / Revocation of this policy will be at the guidance of the Governing Board as evidenced by Governing Board meeting.</p> <p>Staff annual competencies including Abuse/Neglect training during orientation will be performed</p>	11/19/2021

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	<p>ASSESSMENT", policy # MSC.10.3A, indicated competency assessment will occur on an ongoing basis. The continuum will include assessment during the initial competencies, orientation period, and ongoing annual competency assessment. This policy was effective on 10/01/2013.</p> <p>2. The facility policy titled, "ELEMENTS OF ORIENTATION/COMPETENCY", policy # MSC.10.38, indicated staff will complete a position competency upon hire and annually. This policy was effective on 10/01/2013.</p> <p>3. The facility policy titled, "ABUSE: DEFINED CRITERIA, ASSESSMENT AND REPORTING", policy # MSC.3.04, indicated in-service for staff to identify possible victims of abuse will be given on a yearly basis. It was the policy of the facility to protect patients from real or perceived abuse, neglect or exploitation from anyone, including staff members, students, volunteers, other patients, visitors or family members. This policy was reviewed on 07/01/2019.</p> <p>4. The personnel files were reviewed on 09/28/2021. The files lacked annual competency training documentation for staff members PS # 1 (Certified Scrub Tech-CST), NS # 4 (RN), A # 1 (Materials Manager), PS # 2 (Radiology/Safety Officer), NS # 3 (RN Infection Control Officer) and A # 2 (Administrator). The files lacked abuse/neglect training for staff members A # 2 and PS # 4 (Scribe).</p> <p>5. In interview on 09/28/2021 at approximately 2:28 pm with administrative staff member A # 2, confirmed annual competencies and abuse/neglect training had not been completed and/or were missing from the above staff's personnel files.</p>		<p>and maintained in the Education and competencies binder behind each staff members name.</p> <p>It will be the responsibility of the Quality committee and Admin.</p>	

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S 1188 Bldg. 00	<p>6. In interview on 09/29/2021 at approximately 11:00 am with A # 2 and PS # 4, confirmed they had not had abuse/neglect training during orientation.</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(4)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(4) A written fire control plan that contains provisions for the following:</p> <p>(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.</p> <p>Based on document review and interview, the ASC (Ambulatory Surgery Center) failed to ensure the Fire plan was followed for conducting fire drills in 2 of 4 quarters for calendar year end 2020 and thus far 2021. (3rd &amp; 4th quarters 2020).</p> <p>Findings Include:</p> <p>1. Review of ASC policy titled: "FIRE PLAN: CODE RED, policy # EOC.LS.201.00, indicated under PROCEDURE, page 4, "Fire Drills", 3. "There will be at least one fire drill completed each quarter". Effective date - none listed.</p>	S 1188	<p>Safety Management Program will be established in compliance</p> <p>Policy and Procedure regarding the Safety Management Program will be approved by the Governing Board and evidenced within the Governing Board Meeting Minutes.</p> <p>Fire Plan: Code Red EOC. LC.201.00 will be revised to show compliance . Revision/Revocation of this policy</p>	11/19/2021

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S 1196 Bldg. 00	<p>2. Review of ASC's Fire Drill Forms for calendar year end 2020 and thus far 2021, indicated; no documentation was found for a 3rd or 4th quarter fire drill for 2020.</p> <p>3. In Interview with ASC staff member A # 1 (Materials Manager), on 9/28/2021 at approximately 3:00 pm, confirmed the following: A. Is not sure if there were fire drills completed for 3rd &amp; 4th quarters 2020. B. Fire drill documentation for 3rd &amp; 4th quarters, can not be found.</p> <p>4. No other documentation was provided prior to exit.</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAc 15-2.5-7(c)(5)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(5) Maintenance of written evidence of regular inspection and approval by state or local fire control agencies in accordance with center policy and state and local regulations.</p> <p>Based on document review and interview, the ASC (Ambulatory Surgery Center), failed to</p>	S 1196	<p>will be at the guidance of the Governing Board as evidenced by Signatures contained on the policy and the emergency board meeting.</p> <p>Policies will be reviewed no less than every three years and will be addressed during the Governing Body Board Meeting. It will be the responsibility of the Admin to put policies on the agenda for review.</p> <p>Fire drills were completed with documentation for all 4 quarters of 2021 one of which was with the Fire Marshal where the fire alarm was deployed and the Marshall timed MSC on the evacuation.</p> <p>Responsible person is Admin.</p> <p>Safety Management will be established and maintained</p>	11/19/2021	

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	<p>ensure written evidence of a regular local or state fire control inspection in accordance with policy, and state and local regulations.</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>Review of ASC policy titled: "FIRE PLAN: CODE RED", policy # EOC.LS.201.00, indicated under PROCEDURE; under Fire Prevention; a lack of language for regular; annual fire control inspections. Effective date - none listed.</li> <li>Review of fire/building inspection forms for the ASC, indicated that the last Fire/Building Inspection was conducted on 3/5/2019, by the local fire marshal.</li> <li>In interview with ASC staff member A # 1 (Materials Manager) on 9/29/2021 at approximately 8:35 am and at approximately 12:30 pm, confirmed the following: <ol style="list-style-type: none"> <li>That the last fire marshal inspection was in 2019, and one previous in 2018.</li> <li>No other documents were found for fire marshal inspections.</li> </ol> </li> <li>No other documentation was provided prior to exit.</li> </ol>		<p>Policy and procedure regarding the Safety Management Program will be approved by the Governing Body Board as evidenced by signatures on the policies.</p> <p>Fire Plan policy has been reviewed and updated with Governing Board signatures as evidenced on review Effective date has been updated</p> <p>Fire Marshall has inspected the building within the last thirty days as evidenced by documentation kept on site at Michiana Surgery Center with a PASS on all accounts.</p> <p>Fire Marshall inspection will be scheduled by the safety officer yearly. She has been provided the documentation of the previous inspection and will use this to schedule any future inspections.</p>	