

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001071	X2) MULTIPLE CONSTRUCTION A. BUILDING 01 B. WING _____	X3) DATE SURVEY COMPLETED 07/31/2013
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NAME OF PROVIDER OR SUPPLIER MICHIANA ENDOSCOPY CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 53830 GENERATIONS DR STE A SOUTH BEND, IN 46635
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K010000	<p>A Life Safety Code Recertification Survey was conducted by the Indiana State Department of Health in accordance with 42 CFR 416.44(b).</p> <p>Survey Date: 07/31/13</p> <p>Facility Number: 009761 Provider Number: 15C0001071 AIM Number: 200156540A</p> <p>Surveyor: Dennis Austill, Life Safety Code Supervisor</p> <p>At this Life Safety Code survey, Michiana Endoscopy Center was found not in compliance with Requirements for Participation in Medicare/Medicaid, 42 CFR Subpart 416.44(b), Life Safety from Fire and the 2000 edition of the National Fire Protection Association (NFPA) 101, Life Safety Code (LSC), Chapter 21, Existing Ambulatory Health Care Occupancies.</p> <p>This facility located in a one story building determined to be of Type II (111) construction was nonsprinklered. The facility has a fire alarm system with smoke detection in the corridors.</p> <p>Quality Review by Robert Booher, Life</p>	K010000		

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 that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	<p>Safety Code Specialist-Medical Surveyor on 08/09/13.</p> <p>The facility was found not in compliance with the aforementioned regulatory requirements as evidenced by the following:</p>			

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K010021	<p>416.44(b)(1) LIFE SAFETY CODE STANDARD Any door with a required fire protection rating, such as stairways, exit passageways, horizontal exits, smoke barriers, or hazardous area enclosures, if held open, is arranged to close automatically by the actuation of the manual fire alarm system and either smoke detectors arranged to detect smoke on either side of the opening or a complete automatic sprinkler system. 20.2.2.3, 21.2.2.3</p> <p>Based on observation, record review and interview; the facility failed to ensure 1 of 1 doors in the fire barrier wall separating the facility from another occupancy would close automatically. This deficient practice could affect all occupants.</p> <p>Findings include:</p> <p>Based on review of the facility floor life safety plan (A-2) on 07/31/13 at 11:15 a.m., there is a two hour fire rated occupancy separation wall identified.</p> <p>Based on observation during a tour of the facility with the Clinical Director from 12:30 p.m. to 1:30 p.m., the door within the two hour fire wall that separates the ambulatory surgery center from the lab lacked a door closer. Based on interview at the time of observation, the Clinical Director acknowledged the door lacked a door closer.</p>	K010021	<p>Door Closer 416.44(b)(1)LIFE SAFETY CODE STANDARD PLAN OF CORRECTION: The Center will comply with NFPA 38.3.2,39.3.2 related to hazardous areas separated from other parts of the building by fire barriers have at least one hour fire resistance rating or such areas are enclosed with partitions and doors. SYSTEMIC CHANGES: The door within the two hour fire wall that separates the ASC from the lab have had a door self-closing device installed. All fire doors will have proper self-closing devices to provide proper protection from smoke and fire. (Attachment A - work order) RESPONSIBLE PARTY & MONITORING: It is the responsibility of the Center Director to ensure the facility is in compliance with the Life Safety Code Standards. The Center Director or designee will visually inspect for proper door closing and latching. This will be documented on the Environment of Care checklist on a monthly</p>	08/16/2013			

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			basis starting with the August 2013 EOC checklist. The Center Director will report the results to the QAPI Committee for review and recommendation. Recommendations will be submitted to the Governing Body for review and approval.	

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K010046	<p>416.44(b)(1) LIFE SAFETY CODE STANDARD Emergency illumination is provided in accordance with section 7.9. 20.2.9.1, 21.2.9.1</p> <p>1. Based on record review, observation and interview; the facility failed to ensure 7 of 7 battery operated emergency lights were tested monthly in accordance with LSC 7.9. LSC 7.9.3 Periodic Testing of Emergency Lighting Equipment requires a functional test shall be conducted on every required battery powered emergency lighting system at 30 day intervals for a minimum of 30 seconds. Written records of visual inspections and tests shall be kept by the owner for inspection by the authority having jurisdiction. This deficient practice could affect all patients and staff.</p> <p>Findings include:</p> <p>Based on review of the "Facilities and Environment Checklist" with the Clinical Director on 07/31/13 at 11:30 a.m., the policy stated, emergency egress lighting to be tested for 30 seconds monthly, however, documentation of a monthly, 30 second test for the battery operated emergency lights was lacking for 9/12, 11/12, 1/13, 3/13, and 4/13. Based on interview at the time of record review, the Clinical Director acknowledged monthly testing was not complete. Based on</p>	K010046	<p>Battery Powered Lights 416.44(b)(1) LIFE SAFETY CODE - Emergency Illumination Section 7.9.20..2.9.1,21.2.9.1 PLAN OF CORRECTION: The Center will perform monthly 30 second and annual 90 minute testing of all battery powered emergency lights. The Center Director will ensure all battery back up lights are tested monthly for 30 seconds and annually for at least 90 minutes to ensure proper operation and that results of all tests are recorded appropriately on the maintenance record. Any nonoperational units that are discovered during testing will be repaired promptly. SYSTEMATIC CHANGES: Appropriate staff have been provided education on the importance of performing 30 second and 90 minute tests on back up battery powered lights. (Attachment) This task has been added to the facility EOC Checklist. RESPONSIBLE PARTY/MONITORING: The Center Director will monitor maintenance logs for evidence of tests being performed appropriately.</p>	08/16/2013			

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	<p>observation during a tour of the facility with the Clinical Director from 12:30 p.m. to 1:30 p.m., seven battery operated emergency lights were located throughout the facility and illuminated when the battery was tested.</p> <p>2. Based on record review, observation and interview; the facility failed to ensure 7 of 7 battery operated emergency lights provided emergency lighting of at least 1½ hour duration in accordance with LSC 7.9. LSC 7.9.3 Periodic Testing of Emergency Lighting Equipment requires an annual test shall be conducted on every required battery powered emergency lighting system for not less than 1½ hr duration. Equipment shall be fully operational for the duration of the test. Written records shall be kept by the owner for inspection by the authority having jurisdiction. This deficient practice could affect all patients and staff.</p> <p>Findings include:</p> <p>Based on review of the "Facilities and Environment Checklist" with the Clinical Director on 07/31/13 at 11:30 a.m., the policy stated, emergency egress lighting to be tested for 90 minutes annually, however, there was no written record of annual 90 minute duration testing regarding the battery operated emergency</p>			

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	lights available for review. Based on interview at the time of record review, the Clinical Director acknowledged the 90 minute duration testing was conducted in conjunction with the property management company but the facility did not have any documentation. Based on observation during a tour of the facility with the Clinical Director from 12:30 p.m. to 1:30 p.m., seven battery operated emergency lights were located throughout the facility and illuminated when the battery was tested.			

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K010048	<p>416.44(b)(1) LIFE SAFETY CODE STANDARD There is a written plan for the protection of all patients and for their evacuation in the event of an emergency. 20.7.1.1, 21.7.1.1 Based on record review and interview, the facility failed to provide a complete written plan containing procedures to be followed in the event the fire alarm system has to be placed out of service for 4 hours or more in a 24 hour period in accordance with LSC, Section 9.6.1.8 which requires the authority having jurisdiction be notified and the building evacuated or an approved fire watch provided until the fire alarm system has been returned to service. This deficient practice could affect all patients and staff.</p> <p>Findings include:</p> <p>Based on review of "Fire Plan-Fire Watch" documentation with the Clinical Director during record review at 2:30 p.m. on 07/31/13, the facility's written policy in the event the fire alarm system is out of service for four hours or more in a twenty four hour period did not include notification of the Indiana State Department of Health which is the authority having jurisdiction. Based on interview at the time of record review, the Clinical Director acknowledged the written fire watch policy did not include notification of the Indiana State</p>	K010048	<p>Fire Watch Plan PLAN OF CORRECTION: The facility will have a written plan for the protection of all patients and for their evacuation in the event of an emergency. SYSTEMIC CHANGES: The Center Director has revised the fire safety plan / fire watch plan, in the event the fire alarm system were to fail for more than four hours in a 24-hour period, to include notification of the Indiana State Department of Health (ISDH) (Attachment G – Fire Watch Plan) RESPONSIBLE PARTY & MONITORING The Center Director will be responsible for compliance with 2000 NFPA 20.7.1.1, 21.7.1.1. The written fire safety plan will be revised as necessary when regulations change but as a minimum as part of the annual policy and procedure review. POLICY: The Center establishes and maintains a fire plan. PURPOSE: To protect patients, personnel and visitors in the event of a fire PROCEDURE: Do not assume a fire is too small to report. If you find a fire in your area, follow the R.A.C.E. Method: Rescue · Rescue all patients from immediate danger. Protect patients, visitors and personnel from smoke and flames. Activate</p>	09/10/2013			

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	Department of Health in the event the fire alarm system is out of service for four hours or more in a twenty four hour period.		<ul style="list-style-type: none"> · Activate nearest alarm. Alert others in the Center either verbally or through the alarm system. <u>C</u>ontain · Contain the fire by closing all doors and turning off medical gases. (The Center Director or designee evaluates and controls oxygen needs for patients). <u>E</u>xtinguish · Extinguish fire. If the fire is small and contained (for example, trash can) attempt to extinguish fire with portable extinguishers, aiming at the base of the fire. ALWAYS LEAVE AN AVENUE FOR YOUR ESCAPE. IF THE FIRE GETS LARGER – GET OUT AND CLOSE THE DOOR BEHIND YOU. Key Points · Remain calm. · Evacuate patients nearest the fire first. · If fire is suspected behind closed door, feel the door before opening it. If warm, do no open unless a person is trapped inside. · Use telephone for emergencies only. · Evacuate in the opposite direction of the fire. · Stay low in smoke filled area. Breathable air is at the floor level. · Await further instructions. · Place patients awaiting fire evacuation in a safe area close to a fire wall as indicated on evacuation plans. Duties of Center Personnel Assign all personnel a duty in the event of a fire. If the fire is not in your area: Duties of the Center Director · Assist in moving all patients from area of danger and out of the Center if necessary. · Verify that all patients, visitors 		

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			<p>and employees are counted. · Assist Fire Department as necessary. · Evacuate with MSDS book if possible. Duties of Receptionist / Front Office Staff Pull Fire Alarm · Call Fire Department, giving directions and location of fire. · Reassure visitors to remain calm. · Close medical record cabinets. · Be prepared to move patients and visitors to a safe area. Duties of Recovery Personnel · Be prepared to move patients to a safe area. Ambulatory patients move themselves under the direction of the recovery staff. · Close all doors. · Shut off all medical gases in your area. · Assure that all corridors and exits are cleared of possible obstructions. · Bring portable B/P monitor with you. Duties of Nursing Tech Pull Alarm · Close door to area and assist procedure room staff with moving patient to a safe area. Duties of Procedure Room RN · Along with the physician, stabilize the patient and transport if necessary. · Maintain the patient on pulse oximeter. (bring B/P cuff with you) · Green/Purple area: shut off medical gases. Fire Alarms · Fire alarm locations are indicated on the facility map. (Main Entrance and North Door) Fire Extinguishers · Fire extinguisher locations are indicated on the facility map.(Waiting room, Procedure Hall, Back Hall) Fire Plan Education · Fire drills are</p>	

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			<p>conducted quarterly with activation of alarm. Fire Drills · Call the alarm company to notify them of pending drill · Activate the fire alarm · Announced fire drills without evacuation may be performed twice per year · Evacuation drills must be conducted twice per year · After drill complete, call "all clear" · Reset alarm and notify Alarm Company · Record fire drills and responses on the Fire Drill Report Form. Documentation includes:</p> <ul style="list-style-type: none"> o Unobstructed exits and corridors o Function of the fire alarm, detectors and suppression systems o Access to all emergency equipment and personnel o Type of fire condition o Staff response and effectiveness <p>Fire Watch: Protocol for Fire Alarm out of Service: When a required fire alarm system is out of service for more than 4 hours in a 24 hour period, the authority having jurisdiction (Fire Marshal) and the Indiana State Board of Health is notified. · An approved "fire watch" is immediately implemented and continue until the alarm system returns to service. · Fire watch involves assignment of staff to walk the areas affected and monitor for evidence of fire activity. Staff member assigned to fire watch duty have no other assignment or duties during the time of the fire watch. · Staff is trained in fire prevention and notification</p>	

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			techniques. · Staff is instructed to call 911 immediately upon discovering any evidence of fire activity and begin center protocol for code red. · At the time that the alarm system returns to normal function the Fire Marshall is notified and the Fire Watch activities will cease. Actual or false alarms may be documented as a drill, if all components of a drill were addressed (Can only be used for two of the four yearly drills). The QAPI Committee and the Safety Officer assess the drills and recommends applicable improvements. Employees demonstrate their knowledge of the fire plan and fire safety procedures annually.		

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K010050	<p>416.44(b)(1) LIFE SAFETY CODE STANDARD Fire drills are held at unexpected times under varying conditions, at least quarterly on each shift. The staff is familiar with procedures and is aware that drills are part of established routine. 20.7.1.2, 21.7.1.2 Based on record review and interview, the facility failed to ensure fire drills were conducted on every shift during 1 of the past 4 quarters. LSC 21.7.1.2 requires fire drills in ambulatory health care facilities shall include the transmission of a fire alarm signal and simulation of emergency fire conditions. Drills shall be conducted quarterly on each shift to familiarize facility personnel (nurses, interns, maintenance engineers, and administrative staff) with the signals and emergency action required under varied conditions. This deficient practice affects all occupants.</p> <p>Findings include:</p> <p>Based on a review of Fire Drill records provided for the past year with the Clinical Director on 07/31/13 at 12:00 p.m., fire drill training records were not found for the third quarter of 2012 other than an alarm activation on 9/2/12. Based on interview at the time of record review, the Clinical Director acknowledged the fire alarm system went into alarm on 9/2/12 which was a Sunday and no staff</p>	K010050	<p>Fire Drills 416.44(b)(1) LIFE SAFETY CODE STANDARD PLAN OF CORRECTION: The Center will hold quarterly fire drills at unexpected times during hours of operation under varying conditions at least quarterly on each shift. SYSTEMIC CHANGES: On a quarterly basis the center will hold fire drills at various unexpected times of operations of the Center. These drills will include transmission of the fire alarm and simulation of emergency fire conditions. These drills will be documented on the "Fire Drill Report" and evaluation completed by the safety committee to determine if any changes in the procedure are needed. The fire drill evaluation will be reported to the QAPI on a quarterly basis. MONITORING AND RESPONSIBILITY: The Center Director will be responsible for the quarterly fire drill and follow up. Reports will be provided to the QAPI committee.</p>	07/31/2013			

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K010070	<p>416.44(b)(1) LIFE SAFETY CODE STANDARD Portable space heating devices are prohibited except in non-sleeping staff and employee areas where the heating elements of such devices do not exceed 212 degrees F (100 degrees C). 20.7.8, 21.7.8 Based on observation and interview, the facility failed to ensure 1 of 1 space heaters found in in an employee area had a heating element that did not exceed 212 degrees Fahrenheit (F). This deficient practice would not affect patients in the facility but could affect staff.</p> <p>Findings include:</p> <p>Based on observation with the Clinical Director during record review at 2:35 p.m. on 07/31/13, the business office had a portable space heater but it was not in use.</p> <p>Based on interview at the time of observation, the Clinical Director acknowledged the facility does not have a space heater use policy for employee areas and there was no evidence the space heater heating elements would not exceed 212 degrees Fahrenheit.</p>	K010070	<p>Portable Space Heater 416.44 (b) (1) LIFE SAFETY CODE PLAN OF CORRECTION: The Center will comply with Life Safety Code Standard by prohibiting portable space heating devices that exceed 212 degrees F in patient care areas. SYSTEMATIC CHANGES: All portable space heaters were removed from the Center on 7/31/2013. If a portable space heater is used there will be documentation that the heater temperature cannot exceed 212 degrees F and can only be used in employee areas. This will be documented on the EOC checklist on a monthly basis starting with the August 2013 EOC checklist.. RESPONSIBLE PARTY & MONITORING It is the responsibility of the Center Director to ensure that no portable space heater that exceeds 212 degrees F be allowed in the Center.</p>	07/31/2013			

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K010078	<p>416.44(b)(1) LIFE SAFETY CODE STANDARD Anesthetizing locations are protected in accordance with NFPA 99, Standard for Health Care Facilities and NFPA 101.</p> <p>(a) Shutoff valves are located outside each anesthetizing location and arranged so that shutting off one room or location will not affect others.</p> <p>(b) Relative humidity is maintained equal to or greater than 35%.</p> <p>NFPA 99, 4.3.1.2.3(n) and 5.4.1.1, 20.3.2.2, 21.3.3.2</p> <p>Based on record review and interview, the facility failed to ensure relative humidity was maintained equal or greater than 35 % in 4 of 4 procedure rooms. This deficient practice could affect all patients and staff.</p> <p>Findings include:</p> <p>Based on review of the "Temperature Humidity Log" with the Clinical Director on 07/31/13 at 11:30 a.m., there were at least 70 days since January, 2013 where the humidity level in the four procedure rooms was less than 35 %. The daily log indicated room temperature is to be between 68 and 72 degrees and room humidity is to be between 20 % and 60 %. If either temperature or humidity falls outside these ranges, staff is to notify the Clinical Director. Based on interview at</p>	K010078	<p>Humidity 416.44(b)(1) LIFE SAFETY CODE PLAN OF CORRECTION: The center is requesting a waiver herewith to amend the acceptable relative humidity range to be 20% to 60%. (See Waiver Request Letter). SYSTEMATIC CHANGES: The Center is requesting a waiver to allow for humidity levels of 20-60% within the procedure rooms. This request is based on the CMS Letter (S&C: 13-25-LSC & ASC) dated April 19, 2013 and the ASHREA/ASHE (American Society of Heating, Refrigerating and Air-Conditioning Engineers/American Society for Healthcare Engineering).According to the Addendum d to the ASHRAE/ASHE standard 170-2009 on Ventilation of Health Care Facilities approved on June 26, 2010. Table 7-1 Design</p>	09/10/2013

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	the time of review, the Clinical Director acknowledged humidity in the procedure rooms is to be maintained between 20% and 60 % per corporate policy.		Parameters, Class B and C operating rooms and gastrointestinal endoscopy procedure rooms are required to have a relative humidity of 20% to 60%. If either temperature or humidity is found to be out of range of the new guidelines, the Licensed Nurse in the procedure room will verbally notify the Center Director and adjustments will be made to bring the room temperature and/or humidity into compliance. If necessary, a contractor will be contacted for service. The Center policy on Temperature and Humidity Checks has been attached (Attachment F). Center staff were educated regarding procedure room temperature and humidity ranges and policy. RESPONSIBLE PARTY & MONITORING The Center Director/designee will be responsible for reading and recording the daily temperature and humidity. The Center Director to contact the HVAC company if readings are outside of the acceptable range. The humidity waiver will be reviewed and approved at the Sept 10,2013 Governing Body Meeting GOVERNING BOARD DOCUMENTATION Agenda Item: Humidity requirements CMS has issued a categorical Life Safety Code waiver, permitting humidity ranges of 20-60%. This center is electing to use that waiver, which is in		

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			<p>accordance with CMS document S&C 13-25 and ASHRAE Standard 170-2008 Addendum D (Table 7-1). At the time of any future CMS surveys, the survey team will be informed of the center's election to utilize this waiver. In addition, the reference documents will be kept available for staff and surveyors.</p> <p>ACTION: Center elects to utilize Life Safety Code waiver pertaining to relative humidity.</p> <p>TEMPERATURE HUMIDIDTY LOG</p> <p>Date</p> <p>Room 1</p> <p>T H</p> <p>Room 2</p> <p>T H</p> <p>Room 3</p> <p>T H</p> <p>Room 4</p> <p>T H</p> <p>Comment</p> <p>Initial</p> <p>1</p>		

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K010114	<p>416.44(b)(1) LIFE SAFETY CODE STANDARD Ambulatory health care occupancies are separated from other tenants and occupancies by fire barriers with at least a 1 hour fire resistance rating. Doors in such barriers are solid bonded core wood of 1¾ inches or equivalent and are equipped with a positive latch and closing device. Vision panels, if provided in fire barriers or doors, are fixed fire window assemblies in accordance with 8.2.3.2.2.</p> <p>Based on observation, record review and interview; the facility failed to ensure the door in 1 of 1 fire barrier walls separating tenants was equipped with a self closing device. This deficient practice could affect all occupants.</p> <p>Findings include:</p> <p>Based on review of the facility floor life safety plan (A-2) on 07/31/13 at 11:15 a.m., there is a two hour fire rated occupancy separation wall identified.</p> <p>Based on observation during a tour of the facility with the Clinical Director from 12:30 p.m. to 1:30 p.m., the door within the two hour fire wall that separates the ambulatory surgery center from the lab lacked a door closer. Based on interview at the time of observation, the Clinical Director acknowledged the door lacked a door closer.</p>	K010114	<p>Door Closer 416.44(b)(1)LIFE SAFETY CODE STANDARD PLAN OF CORRECTION: The Center will comply with NFPA 38.3.2,39.3.2 related to hazardous areas separated from other parts of the building by fire barriers have at least one hour fire resistance rating or such areas are enclosed with partitions and doors. SYSTEMIC CHANGES: The door within the two hour fire wall that separates the ASC from the lab have had a door self-closing device installed. All fire doors will have proper self-closing devices to provide proper protection from smoke and fire. (Attachment A - work order) RESPONSIBLE PARTY & MONITORING: It is the responsibility of the Center Director to ensure the facility is in compliance with the Life Safety Code Standards. The Center Director or designee will visually inspect for proper door closing and latching. This will be documented on the Environment of Care checklist on a monthly</p>	08/16/2013			

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			basis starting with the August 2013 EOC checklist. The Center Director will report the results to the QAPI Committee for review and recommendation. Recommendations will be submitted to the Governing Body for review and approval.	