

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001144	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 12/01/2015
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NAME OF PROVIDER OR SUPPLIER COLUMBUS PAIN INSTITUTE	STREET ADDRESS, CITY, STATE, ZIP CODE 2400 N PARK STE 20 COLUMBUS, IN 47203
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Q 0000 Bldg. 00	This visit was for recertification of an ambulatory surgery center. Dates of survey: 11/30/15 to 12/1/15 Facility number: 004546 QA: cjl 12/31/15	Q 0000		
Q 0041 Bldg. 00	416.41(a) CONTRACT SERVICES When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner. Based on document review and interview, the center failed to assure that contracted services were provided in a safe and effective manner for 3 services (security, medical records review and housekeeping) by failing to include one contracted service (security) in the quality assessment and performance improvement (QAPI) program for the past four quarters and failing to maintain personnel file documentation of qualifications, training, or periodic evaluations for any contracted housekeeper or medical records	O 0041	1. The Clinical Manager added Koorsen Fire & Security to the Quality Assurance Committee report & plan. Their services will be monitored quarterly, with the results documented in the quarterly report.2. The Clinical Manager & Practice Manager created orientation checklist, HIPAA	03/30/2016

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>consultant.</p> <p>Findings:</p> <ol style="list-style-type: none"> Review of the policy titled Quality Assurance Plan lacked documentation of contracted security services having been included in the plan. The policy was approved 8/1/13. Review of the policy titled Employment Application and Record indicated the following: Each employee of the Center shall complete an Employment Application Form which shall be maintained in a personnel record along with other pertinent information in the Center. Information indicated to be kept in the personnel records included, but was not limited to the following: Orientation Checklist and Record of continuing education/in-service training. Review of documents titled Committee Reports/Quality Assurance Committee, dated 9/1/15, 6/1/15, 2/6/15 and 11/3/14, lacked documentation of review or evaluation of the contracted service for security. On 11/30/15 at 3:00pm, A1, Clinical Manager, indicated the center's Quality Assurance Committee did not include contracted security services in their 		<p>Associate Agreement, 90 day evaluations, & annual evaluations to be completed by all contracted services including Utilization Review, Med Gas, Waste Management, Generator, Medical Record Review, HVAC, Boiler, Fire & Security, Laundry & Linen, Cleaning Service, and Clinical Engineering. 3. The Clinical Manager added review/evaluation of Koorsen, our contracted fire & security service, to the list of contracted services that are evaluated quarterly in Quality Assurance Committee. 4. The Clinical Manager added Koorsen Fire & Security to the list of our contracted services that get quarterly reviews and yearly evaluations following our survey. 5. The Clinical Manager &</p>		

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Q 0081 Bldg. 00	<p>review or evaluation.</p> <p>5. On 12/1/15 at 10:50am, A1 indicated personnel files were not maintained for any contracted employees.</p> <p>416.43(a), 416.43(c)(1) PROGRAM SCOPE; PROGRAM ACTIVITIES (a)(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.</p>		<p>Practice Manager created personnel files for all contracted services including: Utilization Review, Med Gas, Waste Management, Generator, Medical Record Review, HVAC, Boiler, Fire & Security, Laundry & Linen, Cleaning Service, and Clinical Engineering. This will contain orientation checklist, HIPAA Associate Agreement, 90 day evaluations, & annual evaluations, and license or certifications if applicable.</p>		

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	<p>(a)(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.</p> <p>(c)(1) The ASC must set priorities for its performance improvement activities that -</p> <p>(i) Focus on high risk, high volume, and problem-prone areas.</p> <p>(ii) Consider incidence, prevalence, and severity of problems in those areas.</p> <p>(iii) Affect health outcomes, patient safety, and quality of care.</p> <p>Based on document review and interview, the quality assurance and performance improvement program (QAPI) failed to use measurable quality indicators for 14 services/functions furnished in the Center (biomedical engineering, biohazardous waste disposal, housekeeping, internal laboratory, laundry, nursing, pharmacy, radiology, security, discharge, transfer, infection control, medication errors and response to patient emergency).</p> <p>Findings:</p> <p>1. Review of the policy titled Quality Assurance Plan lacked documentation of how quality indicators would be measured. The policy was approved 8/1/13.</p> <p>2. Review of documents titled Committee Reports/Quality Assurance Committee,</p>	O 0081	<p>1. The Clinical Manager will begin evaluating all services/functions with specific measurable/pertinent standards. Rather than simply stating things are without problem or incident, Each area will be critiqued on specific quality indicators. 2. The Clinical Manager revised the Quality Assurance Committee to include measurable standards for the following services: biomedical engineering, biohazardous waste disposal, housekeeping, internal laboratory, laundry, nursing, pharmacy, radiology, security, discharge, transfer, infection control, medication error, and response to patient emergency. Each of these will be addressed and documented quarterly or more frequently as necessary. 3. The Clinical Manager will begin clearly stating a measurable standard/goal for the following services: biomedical engineering, biohazardous waste disposal, housekeeping, internal laboratory,</p>	03/30/2016

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Q 0084 Bldg. 00	<p>dated 9/1/15, 6/1/15, 2/6/15 and 11/3/14, lacked documentation of quality indicator measurements for the following: biomedical engineering, biohazardous waste disposal, housekeeping, internal laboratory, laundry, nursing, pharmacy, radiology, security, discharge, transfer, infection control, medication errors and response to patient emergency.</p> <p>3. On 11/30/15 at 3:00pm, A1, Clinical Manager, indicated biomedical engineering, biohazardous waste disposal, housekeeping, internal laboratory, laundry, nursing, pharmacy, radiology, security, discharge, transfer, infection control, medication errors, and response to patient emergency did not have measurable standards/goals.</p> <p>416.43(e) GOVERNING BODY RESPONSIBILITIES The governing body must ensure that the QAPI program-</p> <p>(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</p>		laundry, nursing, pharmacy, radiology, security, discharge, transfer, infection control, medication error, and response to patient emergency. The standards will be evaluated quarterly, and documented in the Quality Assurance Committee Report.		

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	<p>implement the QAPI program.</p> <p>Based on document review and interview, the governing body failed to ensure that the quality assurance and performance improvement (QAPI) program specified data collection methods, frequency and details for 2015 quality monitors.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. Review of the policy titled Quality Assurance Plan lacked documentation of data collection methods, frequency and details. The policy was approved 8/1/13. 2. Review of documents titled Committee Reports/Quality Assurance Committee, dated 9/1/15, 6/1/15, 2/6/15 and 11/3/14, lacked documentation of specified data collection methods, frequency or details. 3. On 11/30/15 at 3:00pm, A1, Clinical Manager, indicated the QAPI program had not specified details of data collection methods or frequency for services being monitored. 	O 0084	<ol style="list-style-type: none"> 1. The Clinical Manager will ensure The Quality Assurance and Performance Improvement (QAPI) program will contain specified data collection methods, frequency, and details for quality monitors. Our previous and current plans were not documented thoroughly, however staff will be educated on this new collection process and it will be better recorded. 2. The Clinical Manager will modify our current Quality Assurance and Performance Improvement (QAPI) program to include documented specified data collection methods and frequency/details. This will be reviewed & documented quarterly in Quality Assurance Committee Reports. 3. The Clinical Manager will make certain the Quality Assurance and Performance Improvement (QAPI) specifies details of data collection methods and/or frequency for all services monitored including: biomedical engineering, biohazardous waste disposal, housekeeping, internal laboratory, laundry, nursing, pharmacy, radiology, security, discharge, transfer, infection control, medication error, 	03/30/2016	

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Q 0100 Bldg. 00	<p>416.44 ENVIRONMENT</p> <p>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 Life Safety Code (LSC) recertification survey, Columbus Pain Institute 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 20, New Ambulatory Health Care Occupancies.</p> <p>This one story facility was determined to be of Type V (111) construction and not sprinkled. The facility has a fire alarm system with smoke detection in the corridors and spaces open to the corridors.</p> <p>Based on LSC survey and deficiencies found (see CMS 2567L), it was determined that the facility failed to ensure a written fire safety plan for the protection of all patients and for their evacuation in the event of an emergency (see K 048), failed to ensure 8 photoelectric smoke detectors, 4</p>	O 0100	<p>and response to patient emergency.</p> <p>The Clinical Manager and Practice Manager created a written fire plan following our inspection that contains all 8 of the following: 1. Use of alarms, 2. Transmission of alarms to fire department, 3. Response to alarms, 4. Isolation of fire, 5. Evacuation of immediate area, 6. Evacuation of smoke compartment, 7. Preparation of floors & building for evacuation, 8. Extinguishment of fire; as advised. See Attachment Written Fire Plan The Clinical Manager called our contracted Koorsen Fire & Security following our inspection. They came 1/14/16 and inspected all equipment, and provided us with a report of the findings. Koorsen verbalized they will test the eight photoelectric smoke detectors throughout the facility for sensitivity at least every two years and provide us with test records. See Attachment of Inspection The Clinical Manager met with staff to discuss the cited lack of Fire Alarm Fire Watch Policy. We created a new Fire Alarm Fire Watch Policy as well as log. See Attachment Fire Alarm Fire Watch Policy The</p>	01/27/2016

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Q 0104 Bldg. 00	<p>audible/visual devices, 1 fire alarm panel, and 3 manual pull station boxes, which were all fire alarm system components were functional tested annually and the results of such testing listed clearly on inspection reports to identify all devices had been tested and 8 of 8 smoke detectors were tested for sensitivity every two years (see K 051) and failed to ensure its written fire watch policy addressed all procedures to be followed in this facility in the event the fire alarm system has to be placed out of service for 4 hours or more in a 24 hour period and 3 of 3 boilers had an inspection certificate that was current to ensure the boilers was in safe operating condition (see K 130).</p> <p>The cumulative effect of these systemic problems resulted in the center's inability to ensure that all locations from which it provides services are constructed, arranged and maintained to ensure the provision of quality health care in a safe environment.</p> <p>416.44(b) SAFETY FROM FIRE (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Centers of the 2000 edition of the Life Safety Code of the National Fire Protection</p>		Practice Manager contacted Ellis Mechanical following the inspection to set up two year inspections of the Boiler with tag 324915.		

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	<p>Association, regardless of the number of patients served. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federalregister/code_of_federal-regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.</p> <p>(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, 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> <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>(4) An ASC must be in compliance with Chapter 21.2.9.1, Emergency Lighting, beginning on March 13, 2006.</p> <p>(5) Notwithstanding any provisions of the</p>			

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	<p>2000 edition of the Life Safety Code to the contrary, an ASC may place alcohol-based hand rub dispensers in its facility if:</p> <p>(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;</p> <p>(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;</p> <p>(iii) The dispensers are installed in a manner that adequately protects against inappropriate access; and</p> <p>(iv) The dispensers are installed in accordance with the following provisions:</p> <p>(A) Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m);</p> <p>(B) The maximum individual dispenser fluid capacity shall be:</p> <p>(1) 0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors</p> <p>(2) 0.5 gallons (2.0 liters) for dispensers in suites of rooms</p> <p>(C) The dispensers shall have a minimum horizontal spacing of 4 feet (1.2m) from each other;</p> <p>(D) Not more than an aggregate of 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet;</p> <p>(E) Storage of quantities greater than 5 gallons (18.9 liters) in a single smoke compartment shall meet the requirements of NFPA 30, Flammable and Combustible Liquids Code;</p> <p>(F) The dispensers shall not be installed over or directly adjacent to an ignition source;</p> <p>(G) In locations with carpeted floor</p>			

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	<p>coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments; and</p> <p>(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.</p> <p>Based on document review and interview, the facility failed to ensure a written fire safety plan for the protection of all patients and for their evacuation in the event of an emergency, failed to ensure 8 photoelectric smoke detectors, 4 audible/visual devices, 1 fire alarm panel, and 3 manual pull station boxes, which were all fire alarm system components were functional tested annually and the results of such testing listed clearly on inspection reports to identify all devices had been tested and 8 of 8 smoke detectors were tested for sensitivity every two years and failed to ensure its written fire watch policy addressed all procedures to be followed in this facility in the event the fire alarm system has to be placed out of service for 4 hours or more in a 24 hour period and 3 of 3 boilers had an inspection certificate that was current to ensure the boilers was in safe operating condition.</p> <p>Findings:</p> <p>1. Record review on 01/11/16 at 11:40 a.m. with the clinical manager (CM#1) noted the facility lacked a fire safety plan</p>	O 0104	<p>1 & 2. The Clinical Manager and Practice Manager created a written fire plan following our inspection that contains all 8 of the following: 1. Use of alarms, 2. Transmission of alarms to fire department, 3. Response to alarms, 4. Isolation of fire, 5. Evacuation of immediate area, 6. Evacuation of smoke compartment, 7. Preparation of floors & building for evacuation, 8. Extinguishment of fire; as advised. See Attachment Written Fire Plan 3-8. The Clinical Manager called our contracted Koorsen Fire & Security following our inspection. They came 1/14/16 and inspected all equipment, and provided us with a report of the findings. Koorsen verbalized they will test the eight photoelectric smoke detectors throughout the facility for sensitivity at least every two years and provide us with test records. See Attachment of Inspection 9 & 10. The Clinical Manager met with staff to discuss the cited lack of Fire Alarm Fire Watch Policy. We created a new Fire Alarm Fire Watch Policy as well as log. See Attachment Fire Alarm Fire Watch Policy 11-13. The Practice Manager contacted Ellis Mechanical following the</p>	01/27/2016

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	<p>incorporating the use of the alarm, the transmission of the fire alarm to the fire department, the response to the alarm, the evacuation of the immediate area, the evacuation of the smoke compartment, the preparation of the building for evacuation and extinguishment of a fire.</p> <p>2. This was verified by the clinical manager at the time of record review and acknowledged at the exit conference on 01/11/16 at 2:15 p.m.</p> <p>3. Record review on 01/11/16 at 11:50 a.m. with the clinical manager noted there was no annual fire alarm system inspection records to review to indicate all fire alarm system devices and components had been annually functional tested for the past year.</p> <p>4. Interview with the administrator (A#1) on 01/11/16 at 12:15 p.m. indicated the facility is contracted to have an annual fire alarm system inspection, but the annual fire alarm system inspection was not conducted for the year 2015.</p> <p>5. This was verified by the clinical manager at the time of record review and acknowledged at the exit conference on 01/11/16 at 2:15 p.m.</p>		inspection to set up two year inspections of the Boiler with tag 324915.		

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	<p>6. Record review on 01/11/16 at 12:10 p.m. with the clinical manager noted there was no records available for review to indicate the eight photoelectric smoke detectors throughout the facility had been tested for sensitivity over the past two years.</p> <p>7. Interview with the clinical manager on 01/11/16 at 12:15 p.m. indicated there is no smoke detector sensitivity test records available for review.</p> <p>8. This was verified by the clinical manager at the time of record review and acknowledged at the exit conference on 01/11/16 at 2:15 p.m.</p> <p>9. Review of the Disaster Plan on 01/11/16 at 11:50 a.m. with the clinical manager noted there was no written fire watch policy in the event the fire alarm system had to be placed out of service for four hours or more in a twenty four hour period.</p> <p>10. This was verified by the clinical manager at the time of record review and acknowledged at the exit conference on 01/11/16 at 2:15 p.m.</p> <p>11. Observation with the clinical manager on 01/11/16 at 1:30 p.m. noted the American model boiler located in the</p>			

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Q 0122 Bldg. 00	<p>mechanical room with tagged boiler #324915 lacked an inspection certificate indicating a current two year inspection was conducted of the boiler.</p> <p>12. In interview with the clinical manager on 01/11/16 at 1:40 p.m., it was stated there is no current two year inspection certificate for the American model boiler.</p> <p>13. The lack of a current inspection certificate for the American model boiler was acknowledged by the clinical manager at the exit conference on 01/11/16 at 2:15 p.m.</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</p>			

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	<p>periodically reviewed and amended as appropriate.</p> <p>Based on document review and interview the governing body failed to follow an established processes for reappraising medical staff (MS) privileges for 2 MS members (MD#1 and MD#2) within the past 24 months.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. Review of the policy titled By-Laws of the Medical Staff, indicated, in section B. Delineation of Privileges in General, the following: The basis for privileges determinations...shall include observed clinical performance as well as...and that Privileges determination shall also be based on pertinent information concerning clinical performance obtained from other sources, especially other institutions and health care settings where a practitioner exercises clinical privileges. This information shall be added to and maintained in the MS file. The By-Laws were last approved 8/1/13. 2. Review of credential files for MD#1 and MD#2 lacked documentation of appraisals for observed clinical performance in the center and lacked documentation of clinical performance from other sources. 	O 0122	<p>1-4. The Clinical Manager & Practice Manager reviewed the policy titled By-Laws of the Medical Staff. The application & re-application process for privileges will now include specific delineation of services to be provided by medical staff. Furthermore their clinical performance will be reviewed at least annually. Each physician will be observed by one of their peers at least annually, as well as other clinical measures including infection rates. All will be documented on their annual evaluations.</p>	03/30/2016

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Q 0201 Bldg. 00	<p>3. Review of documents titled Annual Review lacked documentation of appraisals for MD#1 or MD#2 to have included observed clinical performance in the center or clinical performance from an other source.</p> <p>4. On 12/1/15 at 11:15am, A2, Practice Manager, indicated reappraisals/evaluation of the physicians was conducted by A2 and did not include observed clinical performance evaluations or clinical performance information from outside sources.</p> <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 perform the referral test in accordance with the requirements of Part 493 of this chapter. Based on document review and interview, the center failed to possess a valid certificate to provide one laboratory service (glucose testing by glucose monitoring device).</p> <p>Findings:</p>	O 0201	The Clinical Manager and Practice Manager will begin the process for a CLIA waiver. Once approved this will be visible in our PACU.	03/31/2016

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Q 0242 Bldg. 00	<p>1. On 11/30/15 at 12:30pm, A1, Clinical Manager, indicated the center does provide blood sugar/glucose monitoring by means of a glucose monitoring device.</p> <p>2. Review of the policy titled Pre-Op Testing/Lab Orders indicated the following: Glucometer will be used only if patient presents to Center with symptoms. The policy was approved 8/1/13.</p> <p>3. Review of the document titled Blood Glucose Monitoring Protocol, indicated the following: At the nurse's discretion, any patient showing signs of hyper/hypoglycemia will have a blood glucose test performed.</p> <p>4. On 11/30/15 at 12:30pm, A1 indicated the center did not possess a valid certificate to perform laboratory services.</p> <p>416.51(b) INFECTION CONTROL PROGRAM The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented</p>			

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S 0000	<p>nationally recognized infection control guidelines.</p> <p>Based on document review and interview, the facility failed to ensure that employees are infectious disease free for 1 (#3) of 10 personnel files reviewed.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. Review of policy titled Employee Physical Examination (no number or date) indicated employees are required to have certain exams prior to employment with the Center. The pre-employment examination shall include the following: PPD and Hepatitis B. 2. Of ten (10) employment personnel files examined, staff member #3 lacked evidence of hepatitis B status. 3. Staff member #1, in an interview on 12/01/2015 at 1300 hours, indicated that many of the employees in the facility also work at the near by hospital. 	O 0242	<p>The Clinical Manager & Practice Manager are restructuring our employee/nursing personnel files to clearly list each person's hire date, license/certifications, orientation, annual inservices, CPR, infection control, fire life safety, evaluations, job description, post offer physical exam, PPD, Rubella, Rubeola, Varicella, Hep B, and flu so that it will be more easily accessible. All employees are required to have PPD & Hep B vaccinations, as well as documentation of such.</p>	03/30/2016	

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Bldg. 00	This visit was for a State licensure survey. Facility Number: 004546 Dates: 11/30/15 - 12/1/15 QA: cjl 12/31/15	S 0000		
S 0153 Bldg. 00	410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(c) (5) (C) Require that the chief executive officer develop and implement policies and programs for the following: (C) Orientation of all new employees, including contract and agency personnel, to applicable center and personnel policies. Based on document review and interview, the governing body failed to ensure orientation was provided for 2 contracted employees (housekeeper and medical records consultant). Findings: 1. On 11/30/15, A1, Clinical Manager,	S 0153	1-4. The Clinical Manager & Practice Manager created personnel files for all contracted services including: Utilization Review, Med Gas, Waste Management, Generator, Medical	03/30/2016

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S 0310	<p>indicated housekeeping and medical records review were performed by contracted staff.</p> <p>2. Review of the policy titled Employment Application and Record indicated the following: Each employee of the Center shall complete an Employment Application Form which shall be maintained in a personnel record along with other pertinent information in the Center. Information indicated to be kept in the personnel records included, but was not limited to the following: Orientation Checklist and Record of continuing education/in-service training. The policy was approved 8/1/13.</p> <p>3. Review of facility personnel documents and 2015 training documents indicated lack of documentation of a record for or orientation of any housekeeper or medical records consultant.</p> <p>4. On 12/1/15 at 10:50am, A1 indicated personnel files were not maintained for housekeepers or the medical records consultant and no documentation of orientation was available.</p>		<p>Record Review, HVAC, Boiler, Fire & Security, Laundry & Linen, Cleaning Service, and Clinical Engineering. This will contain orientation checklist, HIPAA Associate Agreement, 90 day evaluations, & annual evaluations, and license or certifications if applicable.</p>		
	410 IAC 15-2.4-2				

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Bldg. 00	<p>QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)(1)</p> <p>The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:</p> <p>(1) All services, including services furnished by a contractor. Based on document review and interview, the center failed to include four directly provided services (internal laboratory, maintenance, nursing and radiology) and one contracted service (security) in the quality assessment and performance improvement (QAPI) program for the past four quarters.</p> <p>Findings:</p> <p>1. Review of the policy titled Quality Assurance Plan indicated lack of documentation of laboratory, nursing, or radiology services having been included in the plan. The policy was approved 8/1/13.</p> <p>2. Review of documents titled Committee Reports/Quality Assurance Committee, dated 9/1/15, 6/1/15, 2/6/15 and 11/3/14, indicated lack of documentation of review or evaluation of the directly provided services of internal laboratory, maintenance, nursing, or</p>	S 0310	<p>1. The Clinical Manager added laboratory, nursing, and radiology services to the Quality Assurance Committee report & plan. Their services will be monitored quarterly, with the results documented in the quarterly report. 2. The Clinical Manager added Koorsen Fire & Security, laboratory, maintenance, nursing, and radiology to the list of our contracted services that get documented quarterly reviews and yearly evaluations following our survey. This will be included in the Quality Assurance Committee Reports. 3. The Clinical Manager included internal laboratory, maintenance, nursing, radiology, contracted fire & security reviews and evaluations to the quarterly Quality Assurance Committee Reports.</p>	03/30/2016

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S 0320 Bldg. 00	<p>radiology and the contracted service for security.</p> <p>3. On 11/30/15 at 3:00pm, A1, Clinical Manager, indicated the center's Quality Assurance Committee did not include internal laboratory, maintenance, nursing, radiology, or contracted security services in their review or evaluation.</p> <p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)(2)</p> <p>The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:</p> <p>(2) All functions, including, but not limited to, the following:</p> <p>(A) Discharge and transfer. (B) Infection control. (C) Medication errors. (D) Response to patient emergencies.</p> <p>Based on document review and interview, the center failed to include two functions (discharge and response to patient emergencies) in the quality assessment and performance improvement (QAPI) program for the past four quarters.</p> <p>Findings:</p>	S 0320	<p>1. The Clinical Manager included documentation of discharge to the Quality Assurance Committee Reports to ensure all patients are receiving their instructions as planned. We will begin, effective immediately, inquiring on following day post operative phone calls that patients received their discharge paperwork following their procedures. This</p>	03/30/2016			

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S 0442 Bldg. 00	<p>1. Review of the policy titled Quality Assurance Plan indicated lack of documentation of discharge or response to patient emergencies having been included. The policy was approved 8/1/13.</p> <p>2. Review of documents titled Committee Reports/Quality Assurance Committee, dated 9/1/15, 6/1/15, 2/6/15 and 11/3/14, indicated lack of documentation of review or evaluation of the directly functions of discharge and response to patient emergencies.</p> <p>3. On 11/30/15 at 3:00pm, A1, Clinical Manager, indicated the center's Quality Assurance Committee did not include discharge or response to patient emergencies in their review or evaluation.</p> <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>(E) Reviewing and recommending changes in procedures, policies, and</p>		<p>will be on the quarterly reports. The Clinical Manager also added response to patient emergencies to the Quality Assurance quarterly Committee reports. If no emergencies occur, the timely response to mock drills will be documented. 2-3. The Clinical Manager will review/evaluate the discharge process at least quarterly & document these findings in the Quality Assurance Committee Report. The Clinical Manager will also review/evaluate the response to patient emergencies at least quarterly & document these findings in the Quality Assurance Committee Report.</p>				

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	<p>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 infection control committee failed to ensure that employees are infectious disease free for 1 (#3) of 10 personnel files reviewed.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. Review of policy titled Employee Physical Examination (no number or date) indicated employees are required to have certain exams prior to employment with the Center. The pre-employment examination shall include the following: PPD and Hepatitis B. 2. Of ten (10) employment personnel files examined, staff member #3 lacked evidence of hepatitis B status. 3. Staff member #1, in an interview on 12/01/2015 at 1300 hours, indicated that many of the employees in the facility also work at the near by hospital. 	S 0442	The Clinical Manager & Practice Manager are restructuring our employee/nursing personnel files to clearly list each person's hire date, license/certifications, orientation, annual inservices, CPR, infection control, fire life safety, evaluations, job description, post offer physical exam, PPD, Rubella, Rubeola, Varicella, Hep B, and flu so that it will be more easily accessible. All employees are required to have PPD & Hep B vaccinations, as well as documentation of such.	03/30/2016

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S 0522 Bldg. 00	<p>410 IAC 15-2.5-2 LABORATORY SERVICES 410 IAC 15-2.5-2(f)</p> <p>(f) The center shall assure that all laboratory services provided to its patients are performed in a facility possessing a valid certificate, in accordance with 42 CFR 493 (excluding Subparts F, R, Q, and T) authorizing the performance of testing in the specialty of service or subspecialty of service for level of complexity in which the test is categorized.</p> <p>Based on document review and interview, the center failed to possess a valid certificate to provide one laboratory service (glucose by glucose monitoring device).</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. On 11/30/15 at 12:30pm, A1, Clinical Manager, indicated the center does provide blood sugar/glucose monitoring by means of a glucose monitoring device. 2. Review of the policy titled Pre-Op Testing/Lab Orders indicated the following: Glucometer will be used only if patient presents to Center with symptoms. The policy was approved 8/1/13. 3. Review of the document titled Blood 	S 0522	The Clinical Manager and Practice Manager will begin the process for a CLIA waiver. Once approved this will be visible in our PACU.	03/31/2016

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S 0900 Bldg. 00	<p>Glucose Monitoring Protocol, indicated the following: At the nurse's discretion, any patient showing signs of hyper/hypoglycemia will have a blood glucose test performed.</p> <p>4. On 11/30/15 at 12:30pm, A1 indicated the center did not possess a valid certificate to perform laboratory services.</p> <p>410 IAC 15-2.5-5 PATIENT CARE SERVICES 410 IAC 15-2.5-5(a)</p> <p>(a) All patient care services must meet the needs of the patient, within the scope of the service offered, in accordance with acceptable standards of practice. Patient care services must be under the direction of a qualified person or persons. Patient care services must require the following: Based on document review, observation and interview, the facility failed to ensure that the needs of the patient were being met, in regard to obtaining accurate blood glucose measurements.</p> <p>Findings:</p> <p>1. Review of policy titled Blood Glucose Monitoring Protocol (no number or date) indicated that any patient showing signs of hyper/hypoglycemia will have a blood glucose test performed.</p>	S 0900	The Clinical Manager educated the clinical staff on the glucometer. One Touch Manufacturer recommends solutions be dated upon opening and expire 3 months following. The test strips have an expiration date on the bottle. The recommendation also indicates that if the control test is not in range, retesting should be done & the meter should not be used until the control test is within normal range. Our supplies will be routinely checked by clinical staff every Monday morning for proper	02/29/2016

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	<p>2. Review of One Touch manufacturer's recommendations and instructions indicated the solutions are to be dated when opened and will expire three months after opening, and the test strips expire on the date on the bottle. The recommendations also indicated that if the control tests are not in range, retesting should be done, to not use the meter until readings are within normal range for that testing solution and to call the LifeScan representative.</p> <p>3. While touring the surgical area of the facility on 11/30/2015 at 1330 hours, it was observed that the One Touch Ultra glucose meter and solutions had:</p> <p>A. Opened control solutions that were not dated.</p> <p>B. The bottle of test strips in the kit had expired 10/2015.</p> <p>C. Monthly glucometer test log indicated that on 3/11/2015 and 9/2015, the control readings were out of range.</p> <p>4. Staff member # 1 indicated that there was no followup for monthly test readings that were out of range and that the meter is rarely used.</p>		<p>dates of supplies, and if the control reading is ever out of range the clinical manager will be notified to resolve the problem.</p>		

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S 1148 Bldg. 00	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(3)(A)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(3) Provision must be made for the periodic inspection, preventive maintenance, and repair of the physical plant and equipment by qualified personnel as follows:</p> <p>(A) Operation, maintenance, and spare parts manuals must be available, along with training or instruction, or both, of the appropriate center personnel, in the maintenance and operation of fixed and movable equipment.</p> <p>Based on document review and interview, the center failed to ensure an operation and maintenance manual was available for one piece of equipment (the back-up generator).</p> <p>Findings:</p> <p>1. Review of center documents indicated lack of documentation of an operation or maintenance manual of the back-up generator.</p> <p>2. On 12/1/15 at 10:30am, A2, Practice Manager, indicated the center did not</p>	S 1148	The Clinical Manager contacted Indiana Power & Supply following our survey, and they mailed us the manual for operation and maintenance of our generator. We currently have this manual in our possession.	12/09/2015

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

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FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001144	X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____		X3) DATE SURVEY COMPLETED 12/01/2015
NAME OF PROVIDER OR SUPPLIER COLUMBUS PAIN INSTITUTE			STREET ADDRESS, CITY, STATE, ZIP CODE 2400 N PARK STE 20 COLUMBUS, IN 47203		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
	have available, a manual for operation and maintenance of the back-up generator.				