

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001026	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 01/23/2014
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NAME OF PROVIDER OR SUPPLIER PARKVIEW SURGERYONE	STREET ADDRESS, CITY, STATE, ZIP CODE 11420 PARKVIEW CIRCLE FORT WAYNE, IN 46845
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Q000000	The visit was for a re-certification survey. Facility Number: 005407 Survey Date: 1-21-14 to 1-23-14 Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor Linda Plummer, RN Public Health Nurse Surveyor QA: cloughlin 02/03/14	O000000		
Q000220	416.50 NOTICE - POSTING ... The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable. Based on document review, observation and interview, the center failed to follow its policy/procedure and ensure that the posted patient rights document included 5 of 14 required elements. Findings: 1. The policy/procedure Rights and Responsibilities of Patients (approved 1-14)	O000220	On 2/5/14, the Director of Operations met with the Risk Manager for Parkview Health to review the Patient Rights and Responsibilities brochure and poster. Appropriate changes were made to indicate the provision of all 14 rights in a clear manner. Upon completion of the brochure and poster, the Director of Operations will ensure that the updated documents are posted in	03/05/2014

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>indicated the following: "Patient rights and responsibilities shall be posted in plain view in the lobby ..."</p> <p>2. During an observation on 1-22-14 at 1700 hours, the patient rights document posted in the reception and lobby area failed to indicate a provision for the following patient rights:</p> <ul style="list-style-type: none"> a. a list of the physicians who have financial interest or ownership in the ASC center b. all allegations related to mistreatment, neglect, verbal, mental, sexual and/or physical abuse will be immediately reported to a person in authority and fully documented with reporting all substantiated allegations to the State and/or local authority c. the patient has the right to exercise his or her rights without being subjected to discrimination or reprisal d. the patient has the right to submit grievances regarding treatment or care that is (or fails to be) furnished e. the rights of the patient may be exercised by the person appointed under State law to act on the patient's behalf when a patient is adjudged incompetent under applicable State health and safety laws by a court of proper jurisdiction ...[and] ...any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law if a State court has not adjudged a patient incompetent <p>3. During an interview on 1-22-14 at 1700 hours, staff A1 confirmed that the posted Patient Rights and Responsibilities lacked notice of the 5 patient rights provisions.</p>		<p>plain view and that the brochures are given to patients per center policy. Until the updated brochures and poster are received from the printer, copies of the revised rights and responsibilities will be posted at the ASC front desk and given to patients. On 2/7/14, a list of all physicians with ownership in the center was posted by the Director in the center lobby. All policies and procedures for Patient Rights and Responsibilities were reviewed and revised to reflect the appropriate provision of patient rights. The Quality Improvement committee approved the revisions on 2/27/14. The Medical Staff was advised on 3/6 and the Board of Managers was advised on 3/5/14. Prevention- The Board of Managers delegated ongoing responsibility to the COO and Director of Operations to ensure that the proper information on patient rights and responsibilities are provided to patients and their families/surrogates. The documents will be reviewed on an annual basis. Responsible party- Director of Operations, COO, Quality Improvement Committee and Board of Managers.</p>				

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Q000226	<p>416.50(d)(1), (2), & (3) GRIEVANCES - MISTREATMENT, ABUSE The following criteria must be met:</p> <p>(1) All alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse, must be fully documented.</p> <p>(2) All allegations must be immediately reported to a person in authority in the ASC.</p> <p>Only substantiated allegations must be reported to the State authority or the local authority, or both.</p> <p>Based on document review and interview, the center policy/procedures and notice of patient rights failed to ensure that all allegations of abuse, neglect, or mistreatment which are alleged to have occurred at the center will be fully documented, immediately reported to the responsible person at the center and reported to the State and/or a local authority if substantiated.</p> <p>Findings:</p> <p>1. The policy/procedures titled Patient Rights and Responsibilities (approved 1-14) and Patient Complaints and Grievances (approved 1-14) and Patient Rights and Responsibilities notice failed to indicate a process for immediately reporting to a responsible person and fully documenting any allegations involving mistreatment, neglect, verbal,</p>	0000226	<p>On 2/10/14, the list of contracted services was updated to include vendors for electrical services, elevators, fire alarm monitoring, fire alarm testing, fire extinguishers, annual generator service, medical physics and radiology equipment. The Risk Management Committee was advised on 2/27, the ASC staff on 2/27, Medical Staff on 3/6 and the Board of Managers on 3/5/14. Prevention: The Safety Officer and Director of Operations will review the list of contracted services on an annual basis to ensure accuracy. Responsible Party: Safety Officer, Director of Operations, COO, Risk Management Committee and Board of Directors.</p>	03/05/2014			

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Q000227	<p>mental, sexual, or physical abuse with reporting all substantiated allegations to the State and/or local authority.</p> <p>2. During an interview on 1-22-14 at 1555 hours, staff A1 confirmed that the policy/procedures and Patient Rights and Responsibilities notice lacked the patient rights provision.</p> <p>416.50(e)(1)(i) RESPECT - PROPERTY & PERSON The patient has the right to the following:</p> <p>(i) Be free from any act of discrimination or reprisal.</p> <p>Based on document review and interview, the center policy/procedure and notice of patient rights failed to ensure that a patient or their representative may exercise their rights without fear of reprisal.</p> <p>Findings:</p> <p>1. The policy/procedure Patient Rights and Responsibilities (approved 1-14) and Patient Rights and Responsibilities notice failed to indicate that a patient may exercise their rights without being subjected to discrimination or reprisal.</p> <p>2. During an interview on 1-22-14 at 1605 hours, staff A1 confirmed that the policy/procedure and Patient Rights and</p>	O000227	<p>On 2/5/14, the Director of Operations met with the Risk Manager for Parkview Health to review the Patient Rights and Responsibilities brochure and poster. Appropriate changes were made to indicate the provision of all 14 rights in a clear manner. The brochure and poster are updated to reflect that a patient may exercise their rights without being subjected to discrimination or reprisal. Upon completion of the brochure and poster, the Director of Operations will insure that the updated documents are posted in plain view in the center lobby and that the brochures are given to patients per center policy. Until the updated brochures and poster are received from the printer, copies of the revised rights and responsibilities will be posted at</p>	03/05/2014			

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Q000228	<p>Responsibilities notice lacked the patient rights provision.</p> <p>416.50(e)(1)(ii) EXERCISE OF RIGHTS - GRIEVANCES [(1) The patient has the right to the following:]</p> <p>(ii) Voice grievances regarding treatment or care that is (or fails to be) provided. Based on document review and interview, the center policy/procedure and notice of patient rights failed to ensure that a patient or their representative may voice grievances</p>	O000228	<p>the ASC front desk and given to patients and their families/surrogates. All policies regarding patient rights and responsibilities were reviewed and revised to reflect that a patient may exercise their rights without being subjected to discrimination or reprisal. Staff were educated on 2/27. The Quality Improvement Committee approved the revisions on 2/27. The Medical Staff was advised on 3/6 and the Board of Managers was advised on 3/5/14. Prevention: The Board of Managers delegated ongoing responsibility to the Director of Operations and the COO to ensure proper information on patient rights and responsibilities are provided to patients and their families/surrogates. Federal and state codes will be reviewed on an annual basis to ensure compliance. Responsible Party: Director of Operations, COO, Quality Improvement Committee, Board of Managers.</p> <p>On 2/5/14, the Director of Operations met with the Risk Manager for Parkview Health to review the Patient Rights and Responsibilities brochure and poster. Appropriate changes</p>	03/05/2014	

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	<p>regarding treatment or care they receive (or fail to receive).</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. The policy/procedure Patient Rights and Responsibilities (approved 1-14) and Patient Rights and Responsibilities notice failed to indicate that a patient may voice grievances regarding treatment or care that is (or fails to be) provided. 2. During an interview on 1-22-14 at 1605 hours, staff A1 confirmed that the policy/procedure and Patient Rights and Responsibilities notice lacked the patient rights provision. 		<p>were mad to indicate the provision of all 14 rights in a clear manner. The brochure and poster are updated to reflect that a patient has the right to voice grievances regarding treatment or care that is or fails to be provided. Upon completion of the brochure and poster, the Director of Operations will insure that the updated documents are posted in plain view in the center lobby and that the brochures are given to patients per center policy. Until the updated brochures and poster are received from the printer, copies of the revised rights and repsonsibilities will be posted at the ASC front desk and given to patients and their families/surrogates. All policies regarding patient rights and responsibilities and the policy on Grievances and Patient Complaints were reviewed and revised to reflect that a patient has the right to voice grievances regarding treatment or care that is or fails to be provided. Staff were educated on 2/27. The Quality Improvement Committee approved the revisions on 2/27. The Medical Staff was advised on 3/6 and the Board of Managers was advised on 3/5/14.Prevention: The Board of Managers delegated ongoing responsibility to the Director of Operations and the COO to ensure proper information on patient rights and responsibilities are provided to patients and their</p>		

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Q000230	<p>416.50(e)(2)& (3) EXERCISE OF RIGHTS BY OTHERS (2) If a patient is adjudged incompetent under applicable State health and safety laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf.</p> <p>(3) If a State court has not adjudged a patient incompetent, any legal representative or surrogate designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.</p> <p>Based on document review and interview, the center policy/procedures and notice of patient rights failed to ensure the exercise of patient rights by the legal representative when the patient is determined to be incompetent by a court of law or otherwise where a patient may have designated a legal representative to exercise the patient's rights.</p> <p>Findings:</p> <p>1. The policy/procedure The policy/procedure Patient Rights and Responsibilities (approved 1-14) and</p>	Q000230	<p>families/surrogates. Federal and state codes will be reviewed on an annual basis to ensure compliance. Responsible Party: Director of Operations, COO, Quality Improvement Committee, Board of Managers.</p> <p>On 2/5/14, the Director of Operations met with the Risk Manager for Parkview Health to review the Patient Rights and Responsibilities brochure and poster. Appropriate changes were made to indicate the provision of all 14 rights in a clear manner. The brochure and poster are updated to reflect that the exercise of patient rights by a legal representative when the patient is determined to be incompetent by a court of law or otherwise where a patient may have designated a representative to exercise the patient's rights is ensured. Upon completion of the brochure and poster, the Director of Operations will insure that the</p>	03/05/2014	

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	<p>Patient Rights and Responsibilities notice failed to clearly indicate the following: The rights of the patient may be exercised by the person appointed under State law to act on the patient's behalf when a patient is adjudged incompetent under applicable State health and safety laws by a court of proper jurisdiction ...[and] ...any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law if a State court has not adjudged a patient incompetent.</p> <p>2. During an interview on 1-22-14 at 1610 hours, staff A1 confirmed that the policy/procedure and Patient Rights and Responsibilities notice failed to clearly indicate a provision for the exercise of patient rights when the patient is not competent.</p>		<p>updated documents are posted in plain view in the center lobby and that the brochures are given to patients per center policy. Until the updated brochures and poster are received from the printer, copies of the revised rights and responsibilities will be posted at the ASC front desk and given to patients and their families/surrogates. All policies regarding patient rights and responsibilities were reviewed and revised to reflect the ability of a legal representative or surrogate to exercise the patient's rights. Staff were educated on 2/27. The Quality Improvement Committee approved the revisions on 2/27. The Medical Staff was advised on 3/6 and the Board of Managers was advised on 3/5/14. Prevention: The Board of Managers delegated ongoing responsibility to the Director of Operations and the COO to ensure proper information on patient rights and responsibilities are provided to patients and their families/surrogates. Federal and state codes will be reviewed on an annual basis to ensure compliance. Responsible Party: Director of Operations, COO, Quality Improvement Committee, Board of Managers.</p>		

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Q000245	<p>416.51(b)(3) INFECTION CONTROL PROGRAM The program is - Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.</p> <p>Based on review of manufacturer's recommendations, policy and procedure review, observation, and interview, the infection control committee failed to ensure the cleanliness of equipment located while on tour of the facility, failed to ensure the implementation of the policy related to earrings, failed to follow AORN (the association of peri operative nurses) recommendations related to surgical masks, and failed to ensure that the pass through window between the instrument cleaning/decontamination room and the clean room was closed except when passing instruments through.</p> <p>Findings: 1. review of the Skytron warming blanket manufacturer's owner's manual, indicated: a. in section "3-2 Preventative Maintenance", on page 14 it reads: "a. Every 6 months - Cleaning..." and lists 3 steps for cleaning b. in section "3-2 Preventative Maintenance", on page 14 it reads: "b.</p>	Q000245	The Biomedical Department was contacted on 1/24/14 and the specifications from the manufacturer's manual were shared. PMs will be implemented per the manual. A policy on the Use of Warming Cabinets for Blankets was written on 2/11/14. This policy includes procedures on preventative maintenance, cleaning of the unit, maximum temperatures of the unit, daily monitoring and documentation of temperatures and the process to follow if the temperatures are noncompliant. The Infection Control and Quality Improvement Committees provided approval on 2/27. Center staff were inserviced on 2/27 and the Medical Staff were informed on 3/6. The Board of Managers were advised on 3/5/14. Prevention: The nursing staff will monitor warming cabinet temperatures on a daily basis. Out of range temps will be reported and appropriate action taken. The Infection Preventionist and the Safety Officer will monitor documentation of PMs for compliance with manual	03/05/2014			

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	<p>Every year- Internal Cleaning..." and lists 8 steps of internal cleaning</p> <p>c. in section "3-2 Preventative Maintenance", on page 14 it reads: "c. Yearly - Temperature Controller Calibration" and lists 5 steps to be completed</p> <p>2. at 12:05 PM on 1/22/14, while on tour of the PACU (post anesthesia care unit) in the company of staff members #60, the facility administrator, and #61, the surgery manager, it was observed that:</p> <p>a. there was an accumulation of dust in the top cabinet of the Skytron blanket warmer between the lowest (plenum) shelf and the shelf just above it, and in front of the plenum shelf</p> <p>b. the upper cabinet temperature was listed as 133 degrees and the lower cabinet read at 125 degrees</p> <p>3. interview with staff members #60 and #61 at 12:10 PM on 1/22/14, indicated:</p> <p>a. there is no facility policy related to blanket warmers</p> <p>b. there is no monitoring of warming cabinet temperatures</p> <p>4. at 1:50 PM on 1/22/14, while on tour of the surgery area in the company of staff member #61, the surgery manager,</p>		<p>specifications. Responsible Party: Infection Preventionist, Safety Officer, Infection Control Committee, Director of Operations, COO, and Board of Managers. Staff meetings were held on 2/27/14. Education was given by the Infection Preventionist on proper dusting of equipment as part of daily and monthly checks. The Infection Control Committee was advised at the 2/27 meeting, Medical Staff at the 3/6 meeting and the Board of Managers were advised on 3/5/14. Prevention: The Infection Preventionist will monitor the cleaning of equipment as part of daily rounds. Appropriate education will be provided for noncompliance. Appropriate disciplinary action will be taken for further noncompliance. Responsible Party: Infection Preventionist, Director of Operations, COO and Board of Managers. On 2/10/14, the OR Attire Policy was reviewed by the Director of Operations, the OR Manager and the Infection Preventionist and deemed to be appropriate. Reeducation was performed with the Center staff on 2/27 and with the Medical Staff on 3/6 with special emphasis on appropriate covering of ear piercings and the removal of surgical masks at the conclusion of the case. Prevention: The OR Manager and Infection Preventionist will monitor proper operating room attire for 1</p>		

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	<p>it was observed:</p> <p>a. in a hallway outside the decontamination area, it was observed that a code cart had an accumulation of dust on the top of the cart behind the defibrillator</p> <p>b. in the surgery core/hallway area, the Skytron blanket warmer upper cabinet read 127 degrees and the lower cabinet read 139 degrees</p> <p>5. interview at 1:50 PM on 1/22/14 with staff member #61 indicated it was nursing's responsibility to keep the carts clean</p> <p>6. at 10:20 AM on 1/23/14, interview with staff member #60, the facility administrator, indicated:</p> <p>a. after review of bio medical reports, there is no documentation that would indicate the 6 month and annual cleaning and temperature control calibration is being completed, as per manufacturer's recommendations, as listed in 1. above</p> <p>b. it is believed that only electrical checks are being completed by contracted bio medical staff</p> <p>c. without a facility policy, nursing staff are unaware of maximum temperature requirements for the blanket warmers</p>		<p>month. They will report instances of noncompliance of the policy to the Director of Operations, who will follow up with education. If noncompliance continues, appropriate disciplinary action will occur. Responsible Party: OR Manager, Infection Preventionist, Director of Operations, Infection Control Committee, COO, and Board of Managers. On 2/7/14, the CS Dept staff was re-educated by the Infection Preventionist and the OR Manager on the process and theory for separating contaminated and clean work areas in the Dept. Special attention was paid to the importance of keeping the pass through window closed except when being used to pass instruments through. Prevention: The OR Manager and Infection Preventionist will monitor the pass through window in CS for 1 month. They will report instances of noncompliance of the policy to the Director of Operations, who will follow up with education. If noncompliance continues, appropriate disciplinary action will occur. Responsible Party: OR Manager, Infection Preventionist, Director of Operations, Infection Control Committee, COO, and Board of Managers.</p>		

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	<p>7. review of the policy and procedure "Operating Room Attire", no policy number, last reviewed on 7/2013, indicated:</p> <p>a. under "Procedure", on page two, it reads: "...15. Pierced ear jewelry is allowed, but earrings will be covered by the hat..."</p> <p>8. while observing a patient in OR (operating room) #4 at 12:53 PM on 1/22/14, it was observed that three staff had pierced earrings that were not covered by the surgical cap (Rad tech positioning the C-arm, two scrub techs assisting the surgeon--one on each side of the surgical table over the open incisional area)</p> <p>9. interview with staff member #61, the surgery manager, at 1:24 PM on 1/22/14 indicated facility policy requires earrings to be covered by the surgical cap</p> <p>10. at 12:20 PM on 1/22/14, while in the pre op nurses' station in the company of staff member #61, the surgery manager, it was observed that physician #65 was talking with the patient in pre op bay #1 (after coming from the surgery area) with their surgical mask hanging down about the neck</p> <p>11. at 12:37 PM on 1/22/14, while in</p>			

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	<p>the pre op nurses' station, it was observed that a surgical staff member came from the surgery area to converse with another nursing staff member and had their surgical mask down about the neck</p> <p>12. interview with staff member #61, the surgery manager, at 12:25 PM on 1/22/14 indicated:</p> <p>a. AORN recommendations specify that surgical masks are to be removed when leaving the surgery area and are not to be left handing/dangling about the neck</p> <p>b. the current facility policy related to operating room attire does not specify that masks are not to be hanging about the neck</p> <p>13. at 1:45 PM on 1/22/14, while on tour of the central sterilization area, in the company of staff member #61, the surgery manager, it was noted that the pass through window, separating the clean side from the decontamination side, was left standing open (window size approximately 3 feet by 3 feet)</p> <p>14. interview with staff member #61 and the instrument technician at 1:45 PM on 1/22/14 indicated the pass through window was supposed to be closed except when instruments are</p>			

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S000000	<p>being passed through</p> <p>The visit was for a licensure survey.</p> <p>Facility Number: 005407</p> <p>Survey Date: 1-21-14 to 1-23-14</p> <p>Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor</p> <p>Linda Plummer, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 02/03/14</p>	S000000		

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S000226	<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 center failed to maintain a list of all contracted services, including the scope and nature of services provided for 9 of 32 services.</p> <p>Findings:</p> <p>1. Review of a list of contracted services provided by staff A1 failed to indicate a service provider for the following: electrical service, elevators, fire alarm monitoring, fire alarm testing and certification, fire extinguishers, fire sprinklers, annual generator service, medical physics and a radiology equipment service.</p> <p>2. Review of center documentation indicated the following service providers: electrician service by CS1, elevator service by CS2, fire alarm</p>	S000226	<p>On 2/10/14, the list of contracted services was updated to include vendors for electrical services, elevators, fire alarm monitoring, fire alarm testing, fire extinguishers, annual generator service, medical physics and radiology equipment. The Risk Management Committee was advised on 2/27, the ASC staff on 2/27, Medical Staff on 3/6 and the Board of Managers on 3/5/14. Prevention: The Safety Officer and Director of Operations will review the list of contracted services on an annual basis to ensure accuracy. Responsible Party: Safety Officer, Director of Operations, COO, Risk Management Committee and Board of Directors.</p>	03/05/2014			

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	<p>monitoring by CS3, fire alarm testing by CS4, fire extinguisher service by CS5, fire sprinkler service by CS6, annual generator service by CS7, medical physics by CS8 and mini C-arm service by CS9.</p> <p>3. During an interview on 1-22-14 at 1245 hours, staff A1 confirmed that the list of contracted services had not been maintained.</p>			

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S000332	<p>410 IAC 15-2.4-2.2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2.2(a)(1)</p> <p>Sec. 2.2. (a) The center's quality assessment and improvement program under section 2 of this rule shall include the following: (1) A process for determining the occurrence of the following reportable events within the center: (A) The following surgical events: (i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations: (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent; or both (ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. (iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations: (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent; or both (iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded: (AA) Objects intentionally implanted as part of a planned intervention.</p>			
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	<p>(BB) Objects present before surgery that were intentionally retained.</p> <p>(CC) Objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention, such as microneedles or broken screws.</p> <p>(v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.</p> <p>(B) The following product or device events:</p> <p>(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the center. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.</p> <p>(ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:</p> <p>(AA) Catheters.</p> <p>(BB) Drains and other specialized tubes.</p> <p>(CC) Infusion pumps.</p> <p>(DD) Ventilators.</p> <p>(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the center. Excluded are deaths or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.</p> <p>(C) The following patient protection events:</p> <p>(i) Infant discharged to the wrong person.</p> <p>(ii) Patient death or serious disability associated with patient elopement.</p> <p>(iii) Patient suicide or attempted suicide</p>			

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	<p>resulting in serious disability, while being cared for in the center, defined as events that result from patient actions after admission to the center. Excluded are deaths resulting from self inflicted injuries that were the reason for admission to the center.</p> <p>(D) The following care management events: (i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong: (AA) drug; (BB) dose; (CC) patient; (DD) time; (EE) rate; (FF) preparation; or (GG) route of administration. Excluded are reasonable differences in clinical judgment on drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug=drug interactions for which there is known potential for death or serious disability.</p> <p>(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products.</p> <p>(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the center. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following: (AA) Pulmonary or amniotic fluid embolism. (BB) Acute fatty liver of pregnancy. (CC) Cardiomyopathy.</p> <p>(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the center.</p>			

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	<p>(v) Death or serious disability (kernicterus) associated with the failure to identify and treat hyperbilirubinemia in neonates.</p> <p>(vi) Stage 3 or 4 pressure ulcers acquired after admission to the center. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable because of the presence of eschar.</p> <p>(vii) Patient death or serious disability resulting from joint movement therapy performed in the center.</p> <p>(viii) Artificial insemination with the wrong donor sperm or wrong egg.</p> <p>(E) The following environmental events:</p> <p>(i) Patient death or serious disability associated with an electric shock while being cared for in the center. Excluded are events involving planned treatment, such as electrical countershock or elective cardioversion.</p> <p>(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:</p> <p>(AA) contains the wrong gas; or</p> <p>(BB) is contaminated by toxic substances.</p> <p>(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the center.</p> <p>(iv) Patient death or serious disability associated with a fall while being cared for in the center.</p> <p>(v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the center.</p> <p>(F) The following criminal events:</p> <p>(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.</p> <p>(ii) Abduction of a patient of any age.</p> <p>(iii) Sexual assault on a patient within or on</p>			

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	<p>the grounds of the center. (iv) Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the center.</p> <p>Based on document review and interview, the center failed to ensure that all reportable events were identified through the quality assurance/performance improvement (QAPI) program.</p> <p>Findings:</p> <p>1. The policy/procedure Adverse Incident (approved 1-14) failed to indicate the following reportable surgical event: retention of a foreign object in a patient after surgery or other invasive procedure.</p> <p>2. During an interview on 1-22-14 at 1630 hours, staff A1 confirmed that the policy/procedure lacked the surgical event reporting requirement.</p>	S000332	<p>On 2/10/14, the policy on Adverse Incidents was updated to include retention of a foreign object in a patient as a reportable event to the ISDH. The Risk Management Committee was advised on 2/27 and the Board of Managers was advised on 3/5/14. Prevention: The Risk Management Committee and the Director of Operations will review the list of reportable events on an annual basis. Responsible Party: Director of Operations, COO, Risk Management Committee, Board of Managers.</p>	03/05/2014	

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S000334	<p>410 IAC 15-2.4-2.2(a)(2) QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2.2(a)(2)</p> <p>(2) A process for reporting to the department each reportable event listed in subdivision (1) that is determined by the center's quality assessment and improvement program to have occurred within the center.</p> <p>(b) Subject to subsection (e), the process for determining the occurrence of the reportable events listed in subsection (a)(1) by the center's quality assessment and improvement program shall be designed by the center to accurately determine the occurrence of any of the reportable events listed in subsection (a)(1) within the center in a timely manner.</p> <p>(c) Subject to subsection (e), the process for reporting the occurrence of a reportable event listed in subsection (a)(1) shall comply with the following:</p> <p>(1) The report shall:</p> <p>(A) be made to the department;</p> <p>(B) be submitted not later than fifteen (15) working days after the reportable event is determined to have occurred by the center's quality assessment and improvement program;</p> <p>(C) be submitted not later than four (4) months after the potential reportable event is brought to the program's attention; and (D) identify the reportable event, the quarter of occurrence, and the center, but shall not include any identifying information for any:</p> <p>(i) patient;</p> <p>(ii) individual licensed under IC 25; or</p> <p>(iii) center employee involved;</p> <p>or any other information.</p> <p>(2) A potential reportable event may be identified by a center that:</p>			

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	<p>(A) receives a patient as a transfer; or</p> <p>(b) admits a patient subsequent to discharge;</p> <p>from another health care facility subject to a reportable event requirement. In the event that a center identifies a potential reportable event originating from another health care facility subject to a reportable event requirement, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.</p> <p>(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.</p> <p>(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.</p> <p>(d) The center's report of a reportable event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of reportable events occurring within each center. The department's public report will be issued annually.</p> <p>(e) Any serious reportable listed in subsection (a)(1) that:</p> <p>(1) is determined to have occurred within the center between:</p> <p>(A) January 1, 2009; and</p> <p>(B) the effective date of this rule; and</p> <p>(2) has not been previously reported; must be reported within five (5) days of the effective date of this rule. (Indiana State Department of Health; 410 IAC 15-2.4-2.2)</p>			

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S000400	<p>Based on document review and interview, the center lacked a process for reporting each potential reportable event occurrence at the center.</p> <p>Findings:</p> <p>1. The policy/procedure Adverse Incidents (approved 1-14) lacked a provision for reporting potential reportable events identified by state law 410 IAC 15-2.4-2.2(a)(2).</p> <p>2. During an interview on 1-22-14 at 1630 hours, staff A1 confirmed that the policy/procedure lacked a provision for reporting potential reportable events to the ISDH.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(a)</p> <p>(a) The center shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and visitors.</p>	S000334	<p>On 2/10/14, the Adverse Incident Policy was updated to more clearly define the process for reporting potential reportable events identified by state law. The Risk Management Committee was advised on 2/27 and the Board of Managers were advised on 3/5/14. Prevention: The Risk Management Committee and Director of Operations will review the reporting process on an annual basis. Responsible Party: Director of Operations, COO, Risk Management Committee and Board of Managers.</p>	03/05/2014	
	<p>Based on review of manufacturer's recommendations, observation, and interview, the facility failed to ensure the cleanliness of equipment located while on tour of the facility.</p> <p>Findings:</p> <p>1. review of the Skytron warming</p>	S000400	<p>The Biomedical Department was contacted on 1/24/14 and the specifications from the manufacturer's manual were shared. PMs will be implemented per the manual. A policy on the Use of Warming Cabinets for Blankets was written on 2/11/14. This policy includes procedures on preventative maintenance,</p>	03/05/2014	

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	<p>blanket manufacturer's owner's manual, indicated:</p> <p>a. in section "3-2 Preventative Maintenance", on page 14 it reads: "a. Every 6 months - Cleaning..." and lists 3 steps for cleaning</p> <p>b. in section "3-2 Preventative Maintenance", on page 14 it reads: "b. Every year- Internal Cleaning..." and lists 8 steps of internal cleaning</p> <p>c. in section "3-2 Preventative Maintenance", on page 14 it reads: "c. Yearly - Temperature Controller Calibration" and lists 5 steps to be completed</p> <p>2. at 12:05 PM on 1/22/14, while on tour of the PACU (post anesthesia care unit) in the company of staff members #60, the facility administrator, and #61, the surgery manager, it was observed that:</p> <p>a. there was an accumulation of dust in the top cabinet of the Skytron blanket warmer between the lowest (plenum) shelf and the shelf just above it, and in front of the plenum shelf</p> <p>b. the upper cabinet temperature was listed as 133 degrees and the lower cabinet read at 125 degrees</p> <p>3. interview with staff members #60 and #61 at 12:10 PM on 1/22/14, indicated:</p>		<p>cleaning of the unit, maximum temperatures of the unit, daily monitoring and documentation of temperatures and the process to follow if the temperatures are noncompliant. The Infection Control and Quality Improvement Committees provided approval on 2/27. Center staff were inserviced on 2/27 and the Medical Staff were informed on 3/6. The Board of Managers were advised on 3/5/14. Prevention: The nursing staff will monitor warming cabinet temperatures on a daily basis. Out of range temps will be reported and appropriate action taken. The Infection Preventionist and the Safety Officer will monitor documentation of PMs for compliance with manual specifications. Responsible Party: Infection Preventionist, Safety Officer, Infection Control Committee, Director of Operations, COO, and Board of Managers. Staff meetings were held on 2/27/14. Education was given by the Infection Preventionist on proper dusting of equipment as part of daily and monthly checks. The Infection Control Committee was advised at the 2/27 meeting, Medical Staff at the 3/6 meeting and the Board of Managers were advised on 3/5/14. Prevention: The Infection Preventionist will monitor the cleaning of equipment as part of daily rounds. Appropriate</p>		

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	<p>a. there is no facility policy related to blanket warmers</p> <p>b. there is no monitoring of warming cabinet temperatures</p> <p>4. at 1:50 PM on 1/22/14, while on tour of the surgery area in the company of staff member #61, the surgery manager, it was observed:</p> <p>a. in a hallway outside the decontamination area, it was observed that a code cart had an accumulation of dust on the top of the cart behind the defibrillator</p> <p>b. in the surgery core/hallway area, the Skytron blanket warmer upper cabinet read 127 degrees and the lower cabinet read 139 degrees</p> <p>5. interview at 1:50 PM on 1/22/14 with staff member #61 indicated it was nursing's responsibility to keep the carts clean</p> <p>6. at 10:20 AM on 1/23/14, interview with staff member #60, the facility administrator, indicated:</p> <p>a. after review of bio medical reports, there is no documentation that would indicate the 6 month and annual cleaning and temperature control calibration is being completed, as per manufacturer's recommendations, as listed in 1. above</p>		<p>education will be provided for noncompliance. Appropriate disciplinary action will be taken for further noncompliance. Responsible Party: Infection Preventionist, Director of Operations, COO and Board of Managers</p>				

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S000428	<p>b. it is believed that only electrical checks are being completed by contracted bio medical staff</p> <p>c. without a facility policy, nursing staff are unaware of maximum temperature requirements for the blanket warmers</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(i)</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 programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(i) Sanitation. Based on document review, observation and interview, the infection control (IC) committee failed to maintain its sanitation policy/procedures and failed to ensure that the operating room (OR) cleaning was performed in a safe and effective manner.</p> <p>Findings:</p> <p>1. The policy/procedures Housekeeping Services (approved 1-14), Housekeeping Staff Cleaning Techniques - Observation and Evaluation (approved 1-14) and the</p>	S000428	On 2/12/14, the Infection Control Committee updated the policies on Housekeeping Services, Housekeeping Staff Cleaning Techniques-Observation and Evaluation and Cleaning and Disinfecting Schedule to indicate a more specific process for surgical suite cleaning. In addition, the form used for housekeeping observation was updated to reflect the specific process. This form will be utilized in the orientation, competency assurance and observation of cleaning techniques in the OR. The updated policies and forms	03/05/2014	

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S000444	<p>Parkview Surgery One Cleaning and Disinfecting Schedule (updated 1-13) regarding OR rooms failed to indicate IC committee review and approval and failed to indicate a specific process for surgery suite cleaning to prevent contamination of previously disinfected surfaces.</p> <p>2. During an interview on 1-22-14 at 1430 hours, staff A1 and A7 confirmed that the policy/procedures lacked a specific process for cleaning to prevent contamination of previously disinfected surfaces and confirmed that the policy/procedures lacked documentation of IC committee approval.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(ix)</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 programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(ix) Requirements for personal hygiene and attire that meet acceptable standards of practice.</p> <p>Based on policy and procedure review, observation, and staff interview, the</p>	S000444	<p>were approved by the Infection Control Committee on 2/27. Staff were advised on 2/27 and the Board of Managers were advised on 3/5/14. Prevention: Education will be provided by the Infection Preventionist and the Safety Officer to the Housekeeping Staff on 3/3. Annual education and competency assurance will occur and be documented. Any instances of noncompliance will be reported and followed up with re-education. If noncompliance continues, appropriate disciplinary action will occur. Responsible Party: Infection Preventionist, Safety Officer, Infection Control Committee, Director of Operations, COO and Board of Managers.</p> <p>On 2/10/14, the OR Attire Policy was reviewed by the Director of Operations, the OR Manager and</p>	03/05/2014			

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	<p>infection control committee failed to ensure the implementation of policy related to earrings, and failed to follow AORN (the association of peri operative nurses) recommendations related to surgical masks.</p> <p>Findings:</p> <ol style="list-style-type: none"> review of the policy and procedure "Operating Room Attire", no policy number, last reviewed on 7/2013, indicated: <ol style="list-style-type: none"> under "Procedure", on page two, it reads: "...15. Pierced ear jewelry is allowed, but earrings will be covered by the hat..." while observing a patient in OR (operating room) #4 at 12:53 PM on 1/22/14, it was observed that three staff had pierced earrings that were not covered by the surgical cap (Rad tech positioning the C-arm, two scrub techs assisting the surgeon--one on each side of the surgical table over the open incisional area) interview with staff member #61, the surgery manager, at 1:24 PM on 1/22/14 indicated facility policy requires earrings to be covered by the surgical cap at 12:20 PM on 1/22/14, while in the pre op nurses' station in the company of 		<p>the Infection Preventionist and deemed to be appropriate. Reeducation was performed with the Center staff on 2/27 and with the Medical Staff on 3/6 with special emphasis on appropriate covering of ear piercings and the removal of surgical masks at the conclusion of the case. Prevention: The OR Manager and Infection Preventionist will monitor proper operating room attire for 1 month. They will report instances of noncompliance of the policy to the Director of Operations, who will follow up with education. If noncompliance continues, appropriate disciplinary action will occur. Responsible Party: OR Manager, Infection Preventionist, Director of Operations, Infection Control Committee, COO, and Board of Managers.</p>		

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	<p>staff member #61, the surgery manager, it was observed that physician #65 was talking with the patient in pre op bay #1 (after coming from the surgery area) with their surgical mask hanging down about the neck</p> <p>5. at 12:37 PM on 1/22/14, while in the pre op nurses' station, it was observed that a surgical staff member came from the surgery area to converse with another nursing staff member and had their surgical mask down about the neck</p> <p>6. interview with staff member #61, the surgery manager, at 12:25 PM on 1/22/14 indicated:</p> <p>a. AORN recommendations specify that surgical masks are to be removed when leaving the surgery area and are not to be left handing/dangling about the neck</p> <p>b. the current facility policy related to operating room attire does not specify that masks are not to be hanging about the neck</p>			

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S000450	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(g)</p> <p>(g) Sterilization of equipment and supplies must be provided, within the scope of the service offered, in accordance with acceptable standards of practice or manufacturer's recommendations and applicable state laws and rules, 410 IAC 1-4. Sterilization services must be directed by a qualified person or persons and must provide for the following:</p> <p>Based on observation and interview, the infection control committee failed to ensure that the pass through window between the instrument cleaning/decontamination room and the clean room was closed except when passing instruments through.</p> <p>Findings:</p> <ol style="list-style-type: none"> at 1:45 PM on 1/22/14, while on tour of the central sterilization area, in the company of staff member #61, the surgery manager, it was noted that the pass through window, separating the clean side from the decontamination side, was left standing open (window size approximately 3 feet by 3 feet) interview with staff member #61 and the instrument technician at 1:45 PM on 1/22/14 indicated the pass through window was supposed to be closed 	S000450	<p>On 2/7/14, the CS Dept staff was re-educated by the Infection Preventionist and the OR Manager on the process and theory for separating contaminated and clean work areas in the Dept. Special attention was paid to the importance of keeping the pass through window closed except when being used to pass instruments through. Prevention: The OR Manager and Infection Preventionist will monitor the pass through window in CS for 1 month. They will report instances of noncompliance of the policy to the Director of Operations, who will follow up with education. If noncompliance continues, appropriate disciplinary action will occur. Responsible Party: OR Manager, Infection Preventionist, Director of Operations, Infection Control Committee, COO, and Board of Managers.</p>	03/05/2014

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S000466	<p>except when instruments are being passed through</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(g)(3)</p> <p>Sterilization services must be directed by a qualified person or persons and must provide for the following:</p> <p>(3) Records of results must be maintained and evaluated periodically in accordance with 410 IAC 15-2.4-2 to include, but not limited to, the following:</p> <p>(A) Records of recording thermometers or a daily record of the sterilizing cycle (date, time, temperature, pressure, and contents) for each sterilizer load.</p> <p>(B) Results of biological indicators used in testing the sterilizing processes.</p> <p>Based on document review and interview, the infection control committee failed to ensure the documentation of periodic evaluation of sterilization processes and biologicals, as part of infection control and quality committee review.</p> <p>Findings: 1. review of the infection and quality committee meeting minutes for 2013 and January 2014, indicated:</p>	S000466	On 2/27, the Infection Control Committee reviewed the quarterly meeting agenda and determined that they will include the results of sterilization processes and biological reports for evaluation. The Board of Managers was advised on 3/5/14. Prevention: The Infection Preventionist and Director of Operations will implement a Central Sterile Report Card, containing the above information for presentation to the Infection	03/05/2014

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S000920	<p>a. these meetings included infection control practitioner reports and data</p> <p>b. there was no indication that the results of sterilization processes and biological reports were presented/reported to the members</p> <p>2. interview with staff member #64, the infection preventionist, at 1:10 PM on 1/23/14, indicated that currently the sterilization processes and biological reports were not reported to the members at their infection control meetings</p> <p>410 IAC 15-2.5-5 PATIENT CARE SERVICES 410 IAC 15-2.5-5(b)</p> <p>(b) Written patient care policies and procedures shall be available to personnel and shall include, but not be limited to, the following: Based on policy and procedure review, patient medical record review, and staff interview, the facility failed to ensure the implementation of the policy related to pre procedure lab testing for pt. #4.</p> <p>Findings: 1. review of the policy and procedure "PAT Protocols ONE Surgery", no policy number, last dated as revised on</p>	S000920	<p>Control Committee on a quarterly basis. Responsible Party: Infection Preventionist, Director of Operations, COO, Infection Control Committee and Board of Managers.</p> <p>On 2/10, the Preadmission Testing policy was reviewed and revised to allow for the 30 day lab rule to be waived by the anesthesiologist under extenuating circumstances, such as a rescheduled surgery, to avoid duplication of lab services. The anesthesiologist waiving the 30 day time period shall document the waiver in the medical record. Education on the revised policy was performed at</p>	03/05/2014	

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	<p>11/6/13, indicated:</p> <p>a. under "Presurgical Lab Tests", it reads: "All tests are to be completed 5-30 days of surgery unless otherwise specified..."</p> <p>2. review of medical records indicated that patient #4 had:</p> <p>a. surgery on 9/25/13</p> <p>b. labs including, but not limited to, CBC (complete blood count) with no differential, electrolytes, BUN (blood urea nitrogen), and Hemoglobin A1C (glyco hemoglobin), that were done 8/5/13.</p> <p>c. a notation by a physician on 8/6/13 that the patient was "OK for ASC..." (ambulatory surgery center)</p> <p>3. interview with staff member #62, the nurse coordinator in charge of medical records and other duties, at 12:25 PM on 1/23/14, indicated:</p> <p>a. the physician authorizing surgery at the ASC on 8/6/13 did not necessarily mean that these labs would be OK after a 30 day period, as required by facility policy</p> <p>b. it is unknown if the patient was scheduled for surgery within the 30 days of the 8/5/13 lab testing, but had it re scheduled for 9/25/13</p> <p>c. per the policy, and without a physician's comment that the 30 days</p>		<p>the staff meeting on 2/27, the Policy and Procedure Committee on 2/27 and the Medical Staff meeting on 3/6. The Board of Managers was advised on 3/5. Prevention: The Medical Records Clerk will monitor compliance to the policy for a 60 day period. Any instances of noncompliance with the policy will be reported to the Director of Operations, who will follow up with re-education. If noncompliance continues, appropriate disciplinary action will occur. Responsible Party: Director of Operations, COO, Policy and Procedure Committee, Board of Managers.</p>		

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	were waived, the labs for pt. #4 should have been repeated prior to the 9/25/13 surgery to meet policy requirements			