

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING	X3) DATE SURVEY COMPLETED 04/19/2012
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NAME OF PROVIDER OR SUPPLIER INDIANA UNIVERSITY HEALTH SAXONY SURGERY CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 13100 EAST 136TH STREET STE 1100 FISHERS, IN 46037
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S0000	<p>This visit was for a State licensure survey.</p> <p>Facility Number: 012623</p> <p>Survey Date: 4-17/19-12</p> <p>Surveyors: Jack I. Cohen, MHA Medical Surveyor</p> <p>John Lee, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 04/24/12</p>	S0000		

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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S0228	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(e)(4)</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>(4) Ensure that the center maintains a written transfer agreement with one (1) or more hospitals for immediate acceptance of patients who develop complications or require postoperative confinement, and that all physicians, dentists, and podiatrists performing surgery in the center maintain admitting privileges at one (1) or more hospitals in the same county or in an Indiana county adjacent to the county in which the center is located.</p> <p>Based on document review and interview, the governing board failed to assure that 2 of 2 anesthesiologists (MD#1 and MD#5) who were granted privileges for pain management procedures, maintained admitting privileges at one (1) or more hospitals in the same county or in an Indiana county adjacent to the county in which the center is located.</p> <p>Findings:</p> <p>1. Review of 2 physician credential files, MD#1 and MD#5, indicated they were</p>	S0228	<p>Responsible: The clinical manager is responsible to ensure that applications for privileges are complete prior to review by the credentialing committee and board of managers. Corrective Action: Confirmation of admitting and surgical privileges at one or more hospitals in the same or contiguous county will be maintained in the files of physicians performing procedures at the Saxony Surgery Center. The center will confirm admitting and surgical privileges at one or more hospitals in the same or contiguous county for Anesthesiologists who perform</p>	05/01/2012			

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	<p>granted surgery center privileges to include pain management procedures.</p> <p>2. Review of the above-mentioned physician credential files indicated they did not contain documentation the physicians had admitting privileges at one (1) or more hospitals in the same county or in an Indiana county adjacent to the county in which the center is located.</p> <p>3. In interview, on 4-19-12 at 10:30 am, employee #A2 indicated there was no documentation the above-mentioned physicians had admitting privileges at one (1) or more hospitals in the same county or in an Indiana county adjacent to the county in which the center is located. No other documentation was provided by exit.</p>		<p>pain management procedures. The center will confirm anesthesia privileges at one or more hospitals in the same or Indiana contiguous for anesthesiologists who do not perform procedures. Applications for privileges will not be processed without written confirmation of hospital privileges as required.</p>				

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S0310	<p>410 IAC 15-2.4-2 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.</p> <p>Based on document review and interview, the facility failed to include a monitor and standard for 1 directly-provided service in its quality assessment and performance improvement (QAPI) program.</p> <p>Findings:</p> <p>1. Review of the facility's QAPI program indicated it did not include a monitor and standard for the directly-provided service of nursing.</p> <p>2. In interview, on 4-19-12 at 11:45 am, employee #A1 indicated there was no documentation of inclusion of the above activity. No other documentation was provided prior to exit.</p>	S0310	<p>Responsible: The clinical manager is responsible to ensure that the quality plan includes all services, including those furnished by a contractor. The program shall be ongoing and have a written plan of implementation. Corrective Action: A monitor and standard will be added to the quality services monitoring worksheet for the nursing service. The monitoring worksheet will be reviewed monthly. The worksheet is attached as exhibit A.</p>	05/01/2012			

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S0320	<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 facility failed to include a monitor and standard for the activities of discharge and response to patient emergencies in its quality assessment and performance improvement (QAPI) program.</p> <p>Findings:</p> <p>1. Review of the facility's QAPI program indicated it did not include the activities of discharge and response to patient emergencies.</p> <p>2. In interview, on 4-19-12 at 11:45 am, employee #A1 indicated there was no documentation of the inclusion of the above activities. No documentation was provided prior to exit.</p>	S0320	<p>Responsible: The clinical manager is responsible to ensure that the Saxony Surgery Center quality plan includes all required functions. These include discharge and transfer, infection control, medication errors and response to patient emergencies. Corrective Action: The Saxony Surgery Center quality plan has been amended to include discharge activity and response to patient emergency. Response to patient emergencies are reviewed through our internal incident reporting process. The quality plan and discharge criteria tool are attached as exhibit B.</p>	05/01/2012			

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S0332	<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. (BB) Objects present before surgery that were intentionally retained.</p>			

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	<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 resulting in serious disability, while being cared for in the center, defined as events that result from patient actions after admission to</p>			

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	<p>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:</p> <p>(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:</p> <p>(AA) drug; (BB) dose; (CC) patient; (DD) time; (EE) rate; (FF) preparation; or (GG) route of administration.</p> <p>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:</p> <p>(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> <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</p>			

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	<p>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 (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 the grounds of the center.</p> <p>(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>			

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	<p>Based on document review and interview, the facility failed to include a monitor and standard for the activity of reportable events in its quality assessment and performance improvement (QAPI) program.</p> <p>Findings:</p> <ol style="list-style-type: none"> Review of the facility's QAPI program indicated it did not include a monitor and standard for the function of reportable events. In interview, on 4-19-12 at 11:45 am, employee #A1 indicated there was no documentation of inclusion of the above activities. No documentation was provided prior to exit. 	S0332	<p>Responsible: The clinical manager is responsible to ensure that the quality plan and associated reporting and tracking includes reportable events. Corrective Action: The saxony surgery center's quality plan has been amended to include reportable events. Our standard is that all patient incidents including reportable events are tracked the Saxony Surgery Center's incident reporting system and documented for review by the the center's quality committee. All reportable events are reviewed by the board of managers. The center's quality reporting template is attached as Exhibit C.</p>	05/01/2012			

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S0444	<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 document review and observation the facility failed to ensure that surgery center personnel followed established policy/procedures and standards for attire for 1 operating room.</p> <p>Findings include;</p> <p>1. Review of policy/procedure ADM 3.02, Dress Code: Perioperative Practice Domain, indicated the following; "C. Head/Face</p> <p>2. Cloth hats are optional and should consist of standard OR polyester/cotton blend, and should cover all hair. Cloth hats should be laundered when visibly soiled. Wearing disposable bouffant hats over cloth hats is required." This policy/procedure was last reviewed/revised on 02-2012.</p>	S0444	<p>Responsible: The clinical manager is responsible to enforce Saxony Surgery Center policy. Saxony Surgery Center polciy ADMN 3.02 states that "Cloth hats are optional and should consist of standard OR polyester/cotton blend, and should cover all hair. Cloth hats should be laundered when visibly soiled. Wearing disposable bouffant hats over cloth hats is required." Corrective Action: The clinical manager met with center staff on Monday April 23, 2012 to remind all teammates that Saxony Surgery Center policy ADM 3.02 requires that disposable bouffant hats must be worn over cloth hats. This policy will be enforced through the corrective action process. Staff meeting minutes are included as Exhibit D. Ongoing monitoring will occur through direct</p>	04/23/2012			

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	2. On 04-18-12 at 1011 hours in Operating Room 4, the scrub personnel were observed wearing cloth hats with disposable bouffant caps that did not completely cover the cloth hats. The front of the cloth hats were not covered.		observation of OR staff by the Clinical Manager for compliance.		

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S0616	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(c)(3)</p> <p>An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:</p> <p>(3) The center shall use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. Each entry must be authenticated in accordance with the center and medical staff policies.</p> <p>Based on document review and interview, the facility failed to follow its policy for signing a statement that he or she is the only one who has the computer code or password and is the only one to use it for authentication of entries for 4 of 8 physician credential files reviewed.</p> <p>Findings:</p> <p>1. Review of facility policy CLR 6.00, entitled Content of Medical Records, approved February, 2012, indicated any practitioner who uses a computer signature to authenticate entries must sign a statement that he or she is the only one who has the computer code or password and is the only one who will use it. The signed statement must be on file.</p>	S0616	<p>Responsible: The clinical manager is responsible to ensure that applications for privileges are complete prior to review by the credentialing committee and board of managers. Corrective Action: The clinical manager has requested computer confidentiality statements from all physicians on the medical staff. The requirement for confidentiality statements shall be maintained for each credentialed physician. Applications for privileges will not be processed without a completed confidentiality statement as required.</p>	05/21/2012			

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	<p>2. Review of 8 physician credential files indicated files MR#2, MR#5, MR#6 and MR#8 did not contain a signed statement that he or she is the only one who has the computer code or password and is the only one who will use it.</p> <p>3. In interview, on 4-19-12 at 10:30 am, employee #A2 indicated there was no signed statement in the 4 above-mentioned physician credential files and no documentation was provided by exit.</p>			

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NAME OF PROVIDER OR SUPPLIER INDIANA UNIVERSITY HEALTH SAXONY SURGERY CENTER				STREET ADDRESS, CITY, STATE, ZIP CODE 13100 EAST 136TH STREET STE 1100 FISHERS, IN 46037			
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S0826	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(c)(1)(E)</p> <p>The medical staff shall write and implement policies and procedures and the governing body shall approve policies and procedures which include but are not limited to, the following:</p> <p>(E) Safety training required of personnel.</p> <p>Based on document review and interview, the facility failed to provide documentation of safety training in areas where anesthetics are used for 8 of 8 physician credential files reviewed.</p> <p>Findings:</p> <p>1. Review of 8 physician credential files indicated files MD#1, MD#2, MD#3, MD#4, MD#5, MD#6, MD#7 and MD#8 did not contain any documentation of safety training in areas where anesthetics are used.</p> <p>2. In interview, on 4-19-12 at 10:30 am, employee #A2 indicated there was no documentation of the above training and none was provided prior to exit.</p>	S0826	<p>Responsible: The clinical manager is responsible to ensure that safety training of personnel is completed at the Saxony Surgery Center. This is to include physicians working in areas where anesthetics are used. Corrective Action: The clinical manager has developed a physician safety orientation process at the Saxony Surgery Center. The orientation and orientation checklist will be completed with physicians working in areas where anesthetics are used. A copy of the physician safety orientation checklist is attached as exhibit E. Orientation will be included as a part of the credentialing process with documentation maintained in each physician file.</p>	05/21/2012			

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S1166	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(ii)</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>(4) The patient care equipment requirements are as follows:</p> <p>(B) All patient care equipment must be in good working order and regularly serviced and maintained as follows:</p> <p>(ii) There must be evidence of preventive maintenance on all patient care equipment.</p> <p>Based on document review and interview, the facility failed to provide evidence of preventive maintenance (PM) on 1 piece of patient care equipment.</p> <p>Findings:</p> <p>1. Review of the facility's PM reports indicated there was no documentation of PM for the operating room swing lights.</p> <p>2. In interview, on 4-19-11 at 12:30 pm, employee #A2 indicated there was no documentation of PM for the operating room swing lights and none was received prior to exit.</p>	S1166	<p>Responsible: The clinical manager is responsible to ensure that patient care equipment is in good working order and included in the facilities preventative maintenance plan for equipment. Corrective Action: All medical equipment in the facility is required to undergo initial inspection and placed in the preventative maintenance program. Equipment is stickered and evidence of current maintenance will be made available upon request. The operating room swing lights were included in the facilities preventative maintenance schedule but documentation was not available until after the survey</p>	05/01/2012

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			was completed. Evidence of preventative maintenance on the requested OR Light is attached as exhibit F.	

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S1178	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(5)(B)</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>(5) The building or buildings, including fixtures, walls, floors, ceiling, and furnishings throughout, must be kept clean and orderly in accordance with current standards of practice, including the following:</p> <p>(B) Refuse, biohazards, infectious wastes, and garbage must be collected, transported, sorted and disposed of by methods that will minimize nuisances or hazards according to federal, state, and local laws and rules.</p> <p>Based on document review and interview, the facility had no policy for the collection, transportation, sorting, storage and disposal of refuse and garbage.</p> <p>Findings:</p> <p>1. Review of facility policies indicated there was no policy for the collection, transportation, sorting, storage and disposal of refuse and garbage.</p> <p>2. In interview, on 4-19-12 at 12:25 pm, employee #A2 indicated there was no</p>	S1178	<p>Responsible: The administrator is responsible to ensure that appropriate policies are available at the Saxony Surgery Center. Corrective Action: Saxony Surgery Center Policy HMW 8.02 Segregation of Trash will be amended with the below updates. An appendix will be added showing the proper segregation of common waste. Policy HMW 8.02 and appendix 1 are included in the plan of correction as exhibit G.G.</p> <p>General Refuse - Any type of waste that does not pose a chemical, biological, infectious, or</p>	05/03/2012			

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	policy for the collection, transportation, sorting, storage and disposal of refuse and garbage. No documentation was provided prior to exit.		sharps hazard. 1. Disposal guidelines General refuse is to be placed into a receptacle that is labeled GENERAL REFUSE and lined with the appropriate plastic bag. Waste baskets will not be marked in this way. Small containers such as waste paper baskets may be lined with brown, black, or clear plastic liners. Large containers will be lined with clear or black plastic liners. Personnel will empty these containers, replace the liner with the appropriate plastic bag and place the waste into designated receptacles. General refuse can be carried in the same cart as bio-hazardous (infectious) waste, ONLY if: All waste in the cart be in intact, sealed bags of appropriate color, and if a bag should fail, open, or spill its contents in any way, all contents are now considered to be bio-hazardous (infectious), and disposed of as such.				

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S1198	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(6)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(6) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.</p> <p>Based on document review and interview, the facility failed to coordinate emergency disaster and preparedness with an appropriate governmental agency and conduct a disaster drill.</p> <p>Findings:</p> <p>1. Review of facility documents indicated there was none regarding the coordination of emergency disaster and preparedness with an appropriate governmental agency.</p> <p>2. In interview, on 4-19-12 at 12:30 pm, employee #A2 indicated there was no documentation of coordination of emergency disaster and preparedness with an appropriate governmental agency. No documentation was provided prior to exit.</p>	S1198	<p>Responsible: The clinical manager is responsible to ensure that emergency disaster and preparedness activities are coordinated appropriately with government agencies. Corrective Action: The clinical manager has made contact with the district 5 planning committee and requested that the Saxony Surgery Center be allowed to participate and coordinate with district 5. The clinical manager or designee is scheduled to participate in the next district 5 meeting and planning session.</p>	05/03/2012			