

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152020	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 03/06/2014
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NAME OF PROVIDER OR SUPPLIER ST VINCENT SETON SPECIALTY HOSPITAL, INDIANAPOLIS	STREET ADDRESS, CITY, STATE, ZIP CODE 8050 TOWNSHIP LINE RD INDIANAPOLIS, IN 46260
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S000000	This visit was for a standard licensure survey. Facility Number: 003350 Survey Date: 3-5/6-14 Surveyors: Jack I. Cohen, MHA Medical Surveyor Jennifer Hembree, RN Public Health Nurse Surveyor Cleone Peterson Medical Surveyor	S000000		
S000272	QA: cloughlin 03/25/14 410 IAC 15-1.4-1 GOVERNING BOARD 410 IAC 15-1.4-1 (a)(7) (a) The governing board is legally responsible for the conduct of the hospital as an institution. The governing board shall do the following: (7) Ensure that there is a hospital-wide, quality assessment and improvement program to evaluate the provision of patient care. Based on document review and interview, the governing board failed to ensure quality activities for 21 contracted services were included in the hospital's quality assessment	S000272	The Master Service Agreement will be updated to include only those ancillary services actually utilized by Seton (as listed below). Cardiac Catheterization Lab Central Processing Department	04/30/2014

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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S000318	<p>performance improvement (QAPI) program in calendar year 2013.</p> <p>Findings:</p> <ol style="list-style-type: none"> Review of a contract between the hospital and St. Vincent Hospital, Indianapolis, indicated the Scope of Services to be provided by St. Vincent Hospital, Indianapolis were: Surgery, Anesthesiology, Recovery, Hyperbaric Oxygen Therapy ("HBO"), Radiological Services (CT Scans, MRIs, X-Rays, Interventional Radiology, Ultrasounds, PET Scans, Hida/Scan/Idium Scan), Endoscopy Services, Nuclear Medicine, Cardiology (ECHO, CVU), CPD, Emergency Services, Laboratory, Pharmacy, and Respiratory Services. Review of other hospital contracts indicated there was a contract for Laundry services. Review of the governing board minutes for calendar year 2013 indicated the governing board did not review any report of quality activities for the contracted services of Anesthesiology, Recovery, Hyperbaric Oxygen Therapy ("HBO"), Radiological Services (Interventional Radiology, Hida/Scan/Idium Scan), Endoscopy Services, Nuclear Medicine, Cardiology (ECHO, CVU), CPD, Emergency Services, Laboratory, Respiratory Services, and Laundry. In interview, on 3-6-14 at 1:45 pm, employee #A2 confirmed the above and no further documentation was provided by exit. <p>410 IAC 15-1.4-1 GOVERNING BOARD 410 IAC 15-1.4-1(c)(6)(F)</p> <p>(c) The governing board is responsible for managing the hospital. The governing board shall do the following: (6) Require that the chief executive</p>		<p>(CPD) Hyperbaric Oxygen Therapy (HBO) MRI Nuclear Medicine PET Scans Radiology Services (Diagnostic) Surgical Services Separate Quality Indicators will be established for these services and reported quarterly to the Board via the dashboards. The dashboards already includes indicators for HBO, Radiology, and Laundry Services. The date of completion is April 30, 2014. Angie Jochem, Manager of Organizational Excellence is the responsible party.</p>	

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	<p>officer develops policies and programs for the following:</p> <p>(F) Ensuring cardiopulmonary resuscitation (CPR) competence in accordance with current standards of practice and hospital policy for all health care workers, including contract and agency personnel, who provide direct patient care.</p> <p>Based on document review and interview, the governing board failed to ensure cardiopulmonary resuscitation (CPR) competence in accordance with standard and hospital policy in one (1) instance.</p> <p>Findings:</p> <p>1. Review of PolicyStat ID: 68338, entitled CPR Competence for Medical Staff Members, approved 03/2011, indicated ... admitting physicians with the specialties listed below must demonstrate CPR competency and do so by Board certification or Board eligibility:</p> <p>Emergency Medicine, Cardiology, Cardiovascular surgery, Vascular surgery, Intensive Care Medicine, Pulmonology</p> <p>2. Review of credential files indicated MD#2 indicated the physician was neither CPR certified nor Board certified/eligible in any of the above-stated categories.</p> <p>3. In interview, on 3-6-14 at 10:10 am, employee #A2 confirmed the above and no other documentation was provided by exit.</p>	S000318	<p>MD#2 is board certified in internal medicine and is board eligible in critical care medicine. The credentialing file for MD#2 has been updated to include board eligibility documentation for critical care medicine. The board certification/board eligibility will be verified with each reappointment. Angie Jochem, Manager of Organizational Excellence, is the responsible party.</p>	03/21/2014

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S000406	<p>410 IAC 15-1.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-1.4-2(a)(1)</p> <p>(a) The hospital shall have an effective, organized, hospital-wide, comprehensive quality assessment and improvement program in which all areas of the hospital participate. 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 have standards, criteria and outcomes for 21 contracted services in the hospital's quality assessment performance improvement (QAPI) program in calendar year 2013.</p> <p>Findings: 1. Review of a contract between the hospital and St. Vincent Hospital, Indianapolis, indicated the Scope of Services to be provided by St. Vincent Hospital, Indianapolis were: Surgery, Anesthesiology, Recovery, Hyperbaric Oxygen Therapy ("HBO"), Radiological Services (CT Scans, MRIs, X-Rays, Interventional Radiology, Ultrasounds, PET Scans, Hida/Scan/Idium Scan), Endoscopy Services, Nuclear Medicine, Cardiology (ECHO, CVU), CPD, Emergency Services. ... Laboratory, Pharmacy, and Respiratory Services. 2. Review of other hospital contracts indicated there was a contract for Laundry</p>	S000406	The Master Service Agreement will be updated to include only those ancillary services actually utilized by Seton (as listed below). Cardiac Catheterization Lab Central Processing Department (CPD) Hyperbaric Oxygen Therapy (HBO) MRI Nuclear Medicine PET Scans Radiology Services (Diagnostic) Surgical Services Separate Quality Indicators will be established for these services and reported quarterly to the Board via the dashboards. The dashboards already includes indicators for HBO, Radiology, and Laundry Services. The date of completion is April 30, 2014. Angie Jochem, Manager of Organizational Excellence is the responsible party.	04/30/2014			

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S000554	<p>services.</p> <p>3. Review of the facility's QAPI program for calendar year 2013 indicated there were no standards, criteria, and outcomes for the contracted services of Surgery, Anesthesiology, Recovery, Hyperbaric Oxygen Therapy ("HBO"), Radiological Services (CT Scans, MRIs, X-Rays, Interventional Radiology, Ultrasounds, PET Scans, Hida/Scan/Igium Scan), Endoscopy Services, Nuclear Medicine, Cardiology (ECHO, CVU), CPD, Emergency Services, Laboratory, Pharmacy, Respiratory Services, and Laundry.</p> <p>4. In interview, on 3-6-14 at 1:45 pm, employee #A2 confirmed the above and no further documentation was provided by exit.</p> <p>410 IAC 15-1.5-2 INFECTION CONTROL 410 IAC 15-1.5-2(a)</p> <p>(a) The hospital shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and visitors.</p> <p>Based on document review, observation and interview, the hospital failed to follow manufacturer instructions for the testing of Metrex Metricide test strips upon opening a new bottle in 1 instance and failed to maintain a clean environment in 2 instances.</p> <p>Findings:</p> <p>1. Review of manufacturer instructions entitled SOLUTION TEST STRIPS FOR MetriCide OPA Plus, section H.3. indicated it is recommended that the testing of positive and negative controls be performed on each</p>	S000554	Log book updated to include step by step manufacturer instructions. The log sheet has been updated to include documentation of testing of the test strips for each newly opened bottle. A new log sheet will be initiated with each newly opened bottle. This was completed March 7, 2014. Theresa Anderson, Site Administrator, is the responsible party. The wheeled computer keyboard and base stands were cleaned during survey on March 6, 2014. An equipment PM has been created to assure ongoing	03/31/2014

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S000592	<p>newly opened test strip bottle of MetriCide OPA Plus Solution Test Strips.</p> <p>2. Review of the document titled MetriCide OPA Plus Solution Testing Log Sheet, dated 10-30-13 through 2-19-14 indicated no testing of positive and negative controls for the test strip container used as indicated by the line item Date Test Strip Bottle First Opened 10-30-13.</p> <p>3. In interview on 3-5-14 at 2:55 pm, employee #A9 confirmed the above log sheet as evidence of testing the solution. At that time, the employee was requested to provide documentation of testing the test strips per manufacturer recommendation. No further documentation was provided prior to exit.</p> <p>4. On 3-5-14 at 2:15 pm in the presence of employee #A4, it was observed in the in the Medical Staff Lounge there was heavy dust covering 2 each wheeled computer keyboard and base stands.</p> <p>5. On 3-5-14 at 2:50 pm in the presence of employee #A4, it was observed in the male staff locker room, there was a great amount of dust on top of the lockers.</p> <p>410 IAC 15-1.5-2 INFECTION CONTROL 410 IAC 15-1.5-2(f)(3)(D)(i)</p> <p>(f) The hospital shall establish an infection control committee to monitor and guide the infection control program in the facility as follows: (3) The infection control committee responsibilities shall include, but not be limited to, the following:</p>		<p>maintenance and cleaning of wheeled computer keyboard and base stands. The equipment PM was established to begin in April 2014. Kevin Webb, Safety Officer/Facilities Manager is the responsible party. The top of the lockers in the male locker room were cleaned during survey on March 6, 2014. Associates were retrained on proper cleaning procedures in March 2014. A copy of the training is maintained in the associate files. Kevin Webb, Safety Officer/Facilities Manager is the responsible party.</p>				

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	<p>(D) 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.</p> <p>Based on document review, observation, and staff interview, the facility failed to ensure that patient rooms were disinfected on a daily basis and at time of discharge nor did the facility ensure the room cleaning policies addressed type of products (i.e. disinfectant) to be used and the frequency required for cleaning.</p> <p>Findings include;</p> <p>1. Facility policy titled "Occupied Patient Room Cleaning" last approved 3/13 failed to address the frequency of room cleaning as well as failed to address that a disinfectant product should be used for cleaning. The policy states "Dispense required cleaning solutions."</p> <p>2. Facility policy titled "Patient Room, Discharge Cleaning" last approved 3/14 failed to address that a disinfectant is to be used in the room. The policy states "Dispense required cleaning solutions."</p> <p>3. Observation of the housekeeping closets on 1 South and 2 South indicated the facility has a dispensing system for cleaning products and there were four (4) types of cleaning products in the closet including CREW bathroom cleaner (no disinfectant properties), GP Forward SC- general all purpose cleaner (no disinfectant properties),</p>	S000592	<p>The policy titled "Occupied Patient Room Cleaning" will be updated to include the cleaning frequency, daily, as well as use of a disinfectant product. The policy titled "Patient Room, Discharge Cleaning" will be updated to include use of a disinfectant product. EVS training program will be updated to emphasize the type and use of each cleaning product available. All EVS associates will be re-trained and educated on the proper use of cleaning products. A copy of the training will be maintained in the associate personnel file. A laminated chemical reference sheet will be located in each EVS closet just above the cleaning products as an on-going reminder/resource for staff to utilize. Small laminated reference cards will be available on all EVS carts. The plan of corrections will be implemented by April 30, 2014. On-going compliance will be monitored via monthly safety rounds. Kevin Webb, Safety Officer/Facilities Manager is the responsible party.</p>	04/30/2014

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S000930	<p>Virex 256 (disinfectant), and glass cleaner (no disinfectant properties). The system was dialed to the all purpose cleaner for dispensing in both closets.</p> <p>4. Staff member #E2 indicated in interview at 10:00 a.m. on 3/6/14 that he/she uses the bathroom cleaner, all purpose cleaner, and the window cleaner to clean the patient rooms. When asked about the Virex, he/she indicated he/she would use it if they "saw a spot of something."</p> <p>5. Staff member #E3 indicated the following in interview at 10:20 a.m. on 3/6/14: (A) He/she uses the Virex to clean in patient rooms, however when asked to describe the cleaning process and what he/she cleans, he/she mentioned other product used and not the Virex. (B) He/she cleans the bedrails and bedside tables "2-3 times a week".</p> <p>6. Staff member #E1 indicated the following in interview beginning at 1:15 p.m. on 3/6/14: (A) The surfaces in the rooms are cleaned on a daily basis with Virex which is a disinfectant. He/she indicated that both Virex and Clorox wipes are used. (B) He/she verified that the facility policy does not address the fact that rooms are to be disinfected on a daily basis.</p> <p>410 IAC 15-1.5-6 NURSING SERVICE 410 IAC 15-1.5-6 (b)(3)</p> <p>(b) The nursing service shall have the following:</p> <p>(3) A registered nurse shall supervise and evaluate the care planned for and provided to each patient.</p>			

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S001024	<p>Based on document review and observation, the facility failed to follow the Fall Prevention policy on 2 of 3 units toured.</p> <p>Findings include;</p> <ol style="list-style-type: none"> 1. Facility policy titled "Falls Prevention" last approved 4/12 states under "HIGH RISK INTERVENTIONS" on page 4: ".....2. A yellow falling star will be placed on the door frame & at the head of the bed." 2. Review of patients #8, 9, and 21 medical records indicated the patients were assessed as a high risk for falls. 3. Observation of the patient care areas beginning at 9:00 a.m. on 3/6/14 indicated that patients #8, 9, and 21 had no falling star sign on the door frame as required by facility policy. 410 IAC 15-1.5-7 PHARMACEUTICAL SERVICES 410 IAC 15-1.5-7 (d)(2)(C) <p>(d) Written policies and procedures shall be developed and implemented that include the following:</p> <p>(2) Ensure the monthly inspection of all areas where drugs and biologicals are stored and which address, but are not limited to, the following:</p> <p>(C) Detection and quarantine of outdated or otherwise unusable drugs and biologicals from general inventory pursuant to their return to the manufacturer, distributor, or</p>	S000930	The falling stars program/policy will be communicated via huddle during the week of April 14-18 as well as included in the staff meeting slides for May 2014 as a refresher/reminder for all clinical staff. This will be monitored by Clinical Leadership on a weekly basis. This will also be included in the monthly safety rounds for on-going compliance. Theresa Anderson, Site-Administrator is the responsible party.	04/18/2014

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S001160	<p>destruction.</p> <p>Based on observation, the pharmacy failed to ensure outdated I.V. solutions were removed from 2 of 2 crash carts observed.</p> <p>Findings include;</p> <p>1. During tour of the patient care areas beginning at 9:00 a.m. on 3/6/14 and accompanied by staff members #N1, N2 and N3, the following was observed: (A) Three (3) bags of .9% Sodium Chloride with an expiration date of 2/1/14 was observed in the crash cart on 2 East. (B) Three (3) bags of .9% Sodium Chloride with an expiration date of 2/1/14 was observed in the crash cart on 2 South.</p> <p>410 IAC 15-1.5-8 PHYSICAL PLANT 410 IAC 15-1.5-8(d)(1)</p> <p>(d) The equipment requirements are as follows:</p> <p>(1) All equipment shall be in good working order and regularly serviced and maintained.</p>	S001024	The expired medications were removed from the crash carts during survey on March 6, 2014. Crash carts are checked on a daily basis however expired medications are identified based on the dates listed on the log sheet when cart stocked/replenished. Beginning April 2014, crash carts will be opened and checked on a monthly basis to ensure no expired medications. Cindy Overton, Pharmacy Manager, is the responsible party	04/30/2014
	<p>Based on document review and interview, the governing board failed to verify compliance with manufacturer's recommendations in 1 instance.</p> <p>Findings:</p> <p>1. In interview on 3-6-14 at 10:00 am, employee #A4 indicated Tridmedx as the hospital's contracted biomedical engineering provider and indicated their use of a waiver</p>	S001160	Seton is currently working with St.Vincent Health and Ascension Health in regards to the current contract with Trimedx to determine if an exception to the contract can be established for Seton in regards to the waiver program. If unable to obtain an exception to the contract the alternative for Seton would be to submit a request of waiver letter to the Indiana State Department of Health. Determination of	05/30/2014

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S001164	<p>for some hospital patient equipment preventative maintenance (PM).</p> <p>2. In interview on 3-6-14 at 10:45 am, employee #A8 indicated Trimedx used an exception reporting method for PM and was granted a waiver.</p> <p>3. On 3-6-14 at 11:00 am, employee #A8 was requested to provide a copy of the waiver specifically granted for the St. Vincent Seton Specialty Hospital and none was provided. No further documentation was provided by exit.</p> <p>410 IAC 15-1.5-8 PHYSICAL PLANT 410 IAC 15-1.5-8(d)(2)(B)</p> <p>(d) The equipment requirements are as follows: (2) There shall be sufficient equipment and space to assure the safe, effective, and timely provision of the available services to patients, as follows: (B) There shall be evidence of preventive maintenance on all equipment.</p> <p>Based on document review and interview, the</p>	S001164	<p>action/next steps should be complete by April 30, 2014. Peter Alexander, Administrator, is the responsible party. St.Vincent Seton Specialty Hospital, Indianapolis submitted a request of waiver letter to the Indiana State Department of Health on May 5, 2014. Seton leadership is currently working with TriMedx to complete an equipment risk assessment for Seton based on the equipment risk score. The equipment risk assessment will be completed by May 30, 2014. Equipment not included in the waiver will be serviced based on manufacturer's recommendations. Attached please find a copy of the waiver letter as well as the Equipment Risk Assessment Criteria. Peter Alexander, Administrator, is the responsible party.</p> <p>Seton is currently working with St.Vincent Health and Ascension Health in regards to the current</p>	05/30/2014

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S001216	<p>hospital failed to provide evidence of preventative maintenance (PM) for 3 pieces of equipment</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. In interview of 3-5-14 at 3:20 pm, employee #A4 was requested to provide PM documentation on a pedal machine/arm bike and climber stairs located in the rehabilitation unit. 2. No documentation was provided by exit on the above 2 pieces of equipment. 3. Review of a document entitled CLEANING AND MAINTENANCE CAMTEC Info Bariatric Bed indicated as a minimum, the unit should be periodically inspected every 6 months. 4. Review of a document entitled Work Order Number 0006639367 CEID: 816333 indicated only annual maintenance was performed on the bed. 5. In interview, on 3-6-14 at 1:10 pm, employee #A4 confirmed the above on the bariatric bed and no further documentation was provided prior to exit. <p>410 IAC 15-1.5-9 RADIOLOGIC SERVICES 410 IAC 15-1.5-9(b)(1)(A)(B)(i)(ii)(iii)(iv)(v)(C) (b) The services that use ionizing radiation shall not compromise the health, safety, and welfare of patients or personnel in accordance</p>		<p>contract with Trimedx to determine if an exception to the contract can be established for Seton in regards to the waiver program. If unable to obtain an exception to the contract the alternative for Seton would be to submit a request of waiver letter to the Indiana State Department of Health. Determination of action/next steps should be complete by April 30, 2014. Peter Alexander, Administrator, is the responsible party. St.Vincent Seton Specialty Hospital, Indianapolis submitted a request of waiver letter to the Indiana State Department of Health on May 5, 2014. Seton leadership is currently working with TriMedx to complete an equipment risk assessment for Seton based on the equipment risk score. The equipment risk assessment will be completed by May 30, 2014. Equipment not included in the waiver will be serviced based on manufacturer's recommendations. Attached please find a copy of the waiver letter as well as the Equipment Risk Assessment Criteria. Peter Alexander, Administrator, is the responsible party.</p>				

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152020		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 03/06/2014	
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S001906	<p>with federal and state rules, as follows:</p> <p>(1) Proper safety precautions shall be maintained against radiation hazards in accordance with the hospital's radiation and safety program as developed by the radiation safety officer. This includes, but is not limited to, the following:</p> <p>(A) Adequate shielding for patients, personnel, and facilities.</p> <p>(B) Procedures for monitoring:</p> <p>(i) skin dosage;</p> <p>(ii) radionuclide contamination;</p> <p>(iii) quality control;</p> <p>(iv) technique charts, where applicable; and</p> <p>(v) handling of hazardous materials.</p> <p>(C) Appropriate storage, use, and disposal of radioactive materials.</p> <p>Based on documentation and interview, the hospital failed to provide approved documentation of the hospital's written procedures for monitoring and storage of skin dosage devices in 1 instance.</p> <p>Findings:</p> <p>1. On 3-5-14 at 3:15 pm, employee #A4 was requested to provide documentation of written procedures for monitoring and storage of skin dosage devices.</p> <p>2. No documentation of written hospital procedures for monitoring and storage of skin dosage devices was provided by exit.</p> <p>410 IAC 15-1.6-6 REHABILITATION SERVICES</p>	S001216	The radiation safety manual is being updated to include St.Vincent Seton Specialty Hospital as an applicable location. This will be completed by April 30, 2014. A designated location for storage of associate badges has been established. This was complete on April 14, 2014. Nancy Hodson, Manager of Clinical Support Services is the responsible party.	04/30/2014			

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	<p>410 IAC 15-1.6-6(b)</p> <p>(b) The services shall be under the direction of a physician qualified by training or experience and supervised by a qualified person or persons.</p> <p>Based on document review and interview, the facility failed to have the rehabilitation services under the direction of a physician qualified by training or experience.</p> <p>Findings:</p> <ol style="list-style-type: none"> In interview, on 3-5-14 at 9:30 am, employee #A1 indicated the facility provided rehabilitation services. In interview, on 3-5-14 at 12:20 pm, employee #A2 indicated physician MD#2 was the director of the facility's rehabilitation services. Review of the credential file of MD#2 indicated there was no documentation of specific training or experience in rehabilitation, orthopedics or physiatry that would indicate the physician was qualified to be the medical director for rehabilitation services. In interview, on 3-5-14 at 12:20 pm, employee #A2 confirmed the above with regard to MD#2 and no further documentation was provided prior to exit. 	S001906	Currently working to obtain a physiatrist to oversee the rehabilitation services provided at Seton. If unable to obtain a physiatrist to provide that service then will obtain specific education and/or training for our current Medical Director. Plan of action to be determined by April 30, 2014. Melanie Holt, Executive Director of Compliance and Business Development is the responsible party.	04/30/2014			