

COPY



IDAHO DEPARTMENT OF
HEALTH & WELFARE

C.L. "BUTCH" OTTER – Governor
RICHARD M. ARMSTRONG – Director

DEBRA RANSOM, R.N., R.H.I.T., Chief
BUREAU OF FACILITY STANDARDS
3232 Elder Street
P.O. Box 83720
Boise, ID 83720-0009
PHONE 208-334-8626
FAX 208-364-1888

CERTIFIED MAIL: 70073020000140388485

February 27, 2013

Denise Rue, Administrator
Sipi Ambulatory Surgery Center
236 Martin Street
Twin Falls, ID 83301

RE: Sipi Ambulatory Surgery Center, Provider #13C0001020

Dear Ms. Rue:

Based on the survey completed at Sipi Ambulatory Surgery Center, on February 21, 2013, by our staff, we have determined Sipi Ambulatory Surgery Center is out of compliance with the Medicare ASC Condition for Coverage of **Quality Assessment and Performance Improvement 42 CFR 416.43**. To participate as a provider of services in the Medicare Program, an ASC must meet all of the Conditions for Coverage established by the Secretary of Health and Human Services.

The deficiencies, which caused this condition to be unmet, substantially limit the capacity of Sipi Ambulatory Surgery Center, to furnish services of an adequate level or quality. The deficiencies are described on the enclosed Statement of Deficiencies/Plan of Correction (CMS-2567).

You have an opportunity to make corrections of those deficiencies, which led to the finding of non-compliance with the Condition for Coverage referenced above by submitting a written Credible Allegation of Compliance/Plan of Correction.

An acceptable Plan of Correction contains the following elements:

- Action that will be taken to correct each specific deficiency cited;
- Description of how the actions will improve the processes that led to the deficiency cited;
- The plan must include the procedure for implementing the acceptable plan of correction

Denise Rue, Administrator
February 27, 2013
Page 2 of 2

- for each deficiency cited;
- A completion date for correction of each deficiency cited must be included;
 - Monitoring and tracking procedures to ensure the PoC is effective in bringing the ASC into compliance, and that the ASC remains in compliance with the regulatory requirements;
 - The plan must include the title of the person responsible for implementing the acceptable plan of correction; and
 - The administrator's signature and the date signed on page 1 of each form.

Such corrections must be achieved and compliance verified by this office, before April 7, 2013. To allow time for a revisit to verify corrections prior to that date, it is important that the completion dates on your Credible Allegation/Plan of Correction show compliance no later than March 28, 2013.

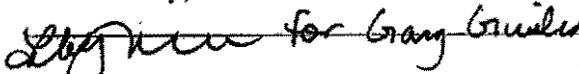
Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **March 11, 2013.**

Failure to correct the deficiencies and achieve compliance will result in our recommending that CMS terminate your approval to participate in the Medicare Program. If you fail to notify us, we will assume you have not corrected.

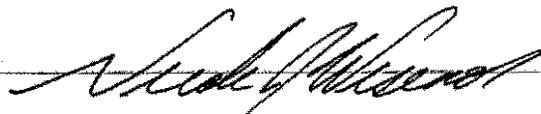
We urge you to begin correction immediately.

If you have any questions regarding this letter or the enclosed reports, please contact me at (208) 334-6626.

Sincerely,



GARY GUILLES
Health Facility Surveyor
Non-Long Term Care



NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

GG/nw

Enclosures

cc: Debra Ransom, R.N., R.H.I.T., Bureau Chief
Kate Mitchell, CMS Region X Office

Southern Idaho Pain Institute P.C.

*236 Martin Street Twin Falls, ID 83301
Phone 208-733-3181 Fax 208-733-3168*

Clinton L. Dillé, M.D.

March 20, 2013

Idaho Dept. of Health & Welfare
Debra Ransom, R.N., R.H.I.T., Chief
Bureau of Facility Standards
3232 Elder Street
PO Box 83720
Boise, Idaho 83720-0009

Completed Plan of Corrections:

Q 080 to Q 083 416.43 (a, b, c, d) Quality Assurance and Performance Improvement (QAPI): Program Scope; Program Activities; Program Data and Performance Improvement Projects

Modifications have been made to the Policy and Procedure regarding "Projects" (V. B. 4.). A copy is attached.

A new data-driven project has been approved by the Governing Body and an introduction completed; a copy is attached.

The QAPI committee will be monitoring the progress of the project.

Q 84 416.43 (e) Governing Body Responsibilities

Modifications have been made to the Governing Body portion of the Policy and Procedure (I. B. 1.) regarding a plan to maintain and ensure a defined QAPI program data-driven project to promote

performance improvement in the overall quality of care and safety within the facility. A copy is attached.

The Governing Body approved a data-driven problem prone project and the introduction is attached.

Q 181 416.48 (a) Administration of Drugs

A second security cabinet has been installed in the clinic. Clinic stocked narcotics and samples have been moved to that double locked cabinet. This cabinet is keyed differently than the cabinet in the Ambulatory Surgery Center (ASC) and the ASC keys are now kept in a secure area when not on the person of the Director of Nursing (DON) who is responsible for the keys and keeping track on a daily basis when the ASC is in operation. Daily counts will be documented by the DON and witnessed counts will be documented monthly. Only the DON, Dr. Dillé and the Administrator will know where the ASC narcotic cupboard keys are kept. Modifications have been made to the Policy and Procedure (VII E. 1. f.) regarding the tracking and securing of stocked scheduled narcotics in the ASC.

Q 242 416.51(b) Infection Control Program

Modifications have been made to the facility's Discharge Instructions to include a section on "Infection" informing patients of some of the signs and symptoms of infection and requesting they call the office if the patient were to develop any of these signs or symptoms. A copy is attached.

Follow-up calls have also been modified to include a reminder for the patient to observe for signs and symptoms of infection and to inform the facility if a question or concern arises of a possible infection. This will be documented in their chart when the information is reviewed.

Additionally, to help ensure infection surveillance, when operative notes are faxed to the patient's primary physician and/or referring physician (if recently referred), a note will be faxed informing their facility to please report to our facility any complaint or awareness of a possible infection reported to or assessed at their facility. (Policy V. D. 3. d. v.)

Modifications have been made to the Policy and Procedure, Infection Control and Surveillance (V. D. 3.) to clarify protocols to improve infection prevention and surveillance. Nationally recognized sources that have been used in the development of any portion of the policy are cited as well. As the policies and procedures are modified or added in the future, sources utilized in these changes will be sited as well.

Thank You,

A handwritten signature in cursive script, appearing to read "Clinton L. Dillé".

Clinton L. Dillé, M.D.

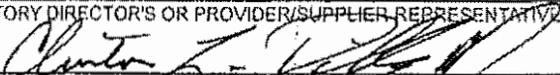
DEPARTMENT OF HEALTH AND HUMAN SERVICES
 SERVICES FOR MEDICARE & MEDICAID SERVICES

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 FORM APPROVED
 OMB NO. 0938-0391

NUMBER OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 13C0001020	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 02/21/2013
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NAME OF PROVIDER OR SUPPLIER SIPI AMBULATORY SURGERY CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 236 MARTIN STREET TWIN FALLS, ID 83301
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
Q 000	<p>INITIAL COMMENTS</p> <p>The following deficiencies were cited during the Medicare recertification survey of your surgery center. Surveyors conducting the recertification were:</p> <p>Gary Guiles, RN HFS, Team Leader Libby Doane, RN, BSN, HFS</p> <p>Acronyms used in this report include:</p> <p>APIC = Association for Professionals in Infection Control and Epidemiology ASC = Ambulatory Surgical Center CDC = Centers for Disease Control CMA = Certified Medical Assistant DON = Director of Nursing PA = Physician's Assistant QAPI = Quality Assessment Performance Improvement RN = Registered Nurse</p>	Q 000	<p>Q 080-Q 083 416.43 (a, b, c, d) QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT</p> <p>In order to meet the goal of implementing and maintaining an effective Quality Assessment and Performance Improvement (QAPI) program, Southern Idaho Pain Institute (SIPI) will revise and implement the present Policy and Procedure to clarify the specific guidelines to follow for on-going quality assessment and performance improvement projects. Although the staff has consistently and actively been involved in ongoing projects, these were not "data-driven". It is of utmost importance in ensuring performance improvement that the staff be involved in "measurable" improvements in order to provide improved patient care, safety, services and health outcomes utilizing quality indicators. Making these modifications to the Policy and</p>	
Q 080	<p>416.43 QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT</p> <p>The ASC must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement (QAPI) program.</p> <p>This CONDITION is not met as evidenced by: Based on staff interview and review of ASC policies and QAPI documents, it was determined the facility failed to ensure a QAPI program had been developed and implemented. This resulted in the inability of the ASC to evaluate its processes and practices. Findings include:</p>	Q 080		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE President	(X6) DATE 3/8/13
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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that her 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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Q 000	<p>INITIAL COMMENTS</p> <p>The following deficiencies were cited during the Medicare recertification survey of your surgery center. Surveyors conducting the recertification were:</p> <p>Gary Gules, RN HFS, Team Leader Libby Doane, RN, BSN, HFS</p> <p>Acronyms used in this report include:</p> <p>APIC = Association for Professionals in Infection Control and Epidemiology ASC = Ambulatory Surgical Center CDC = Centers for Disease Control CMA = Certified Medical Assistant DON = Director of Nursing PA = Physician's Assistant QAPI = Quality Assessment Performance Improvement RN = Registered Nurse</p>	Q 000	Q 080-Q 083 416.43 (a, b, c, d) QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT In order to meet the goal of implementing and maintaining an effective Quality Assessment and Performance Improvement (QAPI) program, Southern Idaho Pain Institute (SIPI) will revise and implement the present Policy and Procedure to clarify the specific guidelines to follow for on-going quality assessment and performance improvement projects. Although the staff has consistently and actively been involved in ongoing projects, these were not "data-driven". It is of utmost importance in ensuring performance improvement that the staff be involved in "measurable" improvements in order to provide improved patient care, safety, services and health outcomes utilizing quality indicators. Making these modifications to the Policy and	
Q 080	<p>416.43 QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT</p> <p>The ASC must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement (QAPI) program.</p> <p>This CONDITION is not met as evidenced by: Based on staff interview and review of ASC policies and QAPI documents, it was determined the facility failed to ensure a QAPI program had been developed and implemented. This resulted in the inability of the ASC to evaluate its processes and practices. Findings include:</p>	Q 080		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE _____ TITLE _____ (X6) DATE _____

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Q 080	Continued From page 1 1. Refer to Q081 as it relates to the failure of the ASC to ensure the scope of the QAPI program provided sufficient direction to staff to allow them to demonstrate measurable improvement in patient health outcomes by using quality indicators. 2. Refer to Q082 as it relates to the failure of the ASC to ensure quality indicator data was collected and used to monitor the effectiveness and safety of its services. 3. Refer to Q083 as it relates to the failure of the ASC to ensure performance improvement projects were developed and conducted. 4. Refer to Q084 as it relates to the failure of the ASC to ensure the governing body defined, implemented and maintained a QAPI program that gathered and collected data in order to evaluate processes of care. The cumulative effect of these negative facility practices prevented the ASC from utilizing information to improve its processes.	Q 080	Procedure will assist in providing a protocol for the staff to refer to if clarification of "data-driven" concerns or questions should arise. The QAPI committee will closely monitor and ensure that the projects are demonstrating measurable improvement in patient health and safety outcomes and quality of care by using quality indicators and/or performance measures. These indicators will focus on high risk, volume and problem prone areas. Incidence, severity and prevalence will be highly considered in choosing said projects. Although no actual "data" was present in the SIFI's 2011-2012 completed projects, these projects were the responsibility of the staff and were very educational, informative and beneficial for improving patient services and care as well as compliance with the Center's policies and procedures. Minutes of monthly staff meetings confirm		
Q 081	416.43(a), 416.43(c)(1) PROGRAM SCOPE; PROGRAM ACTIVITIES (a)(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors. (a)(2) The ASC must measure, analyze, and track quality indicators, adverse patient events,	Q 081			

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Q 081	<p>Continued From page 2</p> <p>infection control and other aspects of performance that includes care and services furnished in the ASC.</p> <p>(c)(1) The ASC must set priorities for its performance improvement activities that -</p> <ul style="list-style-type: none"> (i) Focus on high risk, high volume, and problem-prone areas. (ii) Consider incidence, prevalence, and severity of problems in those areas. (iii) Affect health outcomes, patient safety, and quality of care. <p>This STANDARD is not met as evidenced by: Based on staff interview and review of ASC policies and QAPI documents, it was determined the facility failed to ensure the scope of the QAPI program provided sufficient direction to staff to allow them to demonstrate measurable improvement in patient health outcomes by using quality indicators. This resulted in performance measures that were insufficient to measure the quality of care provided to patients. Findings include:</p> <p>A QAPI plan that identified quality indicators for the ASC to measure had not been developed. No document was present that defined quality indicators for 2012 or 2013. No document was present that required the ASC to gather data or to use data to evaluate processes of care. No document was present that identified the ASC's priorities for its performance improvement activities or that identified high risk, high volume, and problem-prone areas the ASC would focus its</p>	Q 081	<p>the Center's ongoing commitment to provide and involve the staff with quality assessment and performance improvement awareness. These meetings are based almost completely on ongoing evaluation of patient care processes and the staff's adherence to present policies and procedures. However, the SIPI QAPI program must and will diligently strive to satisfy the stated deficiencies by implementing, enforcing and evaluating on going "data-driven" projects in the future to monitor the effectiveness and safety of its services and quality of care. Tracking adverse events, examining their causes and implementing improvements must be sustained over time. Corrective measures will be provided to the staff at the monthly meetings in order to ensure they are familiar with the needs and changes that must be made as a result of the</p>	

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Q 081	<p>Continued From page 3 QAPI efforts on.</p> <p>The DON was interviewed on 2/20/13 beginning at 11:05 AM. She stated she lead the QAPI Committee meetings. She confirmed no quality indicators apart from items listed in patient satisfaction surveys had been developed in 2012 and 2013. She stated only raw data had been collected from the patient satisfaction surveys and the data had not been analyzed or compared with other data. She stated no data had been collected to evaluate patient care processes or to determine if staff were following ASC policies and procedures.</p> <p>The ASC had not developed a quality plan that defined the scope of the QAPI program.</p> <p>Q 082 416.43(b), 416.43(c)(2), 416.43(c)(3) PROGRAM DATA; PROGRAM ACTIVITIES</p> <p>(b)(1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.</p> <p>(b)(2) The ASC must use the data collected to - (i) Monitor the effectiveness and safety of its services, and quality of its care. (ii) Identify opportunities that could lead to improvements and changes in its patient care.</p> <p>(c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.</p> <p>(c)(3) The ASC must implement preventive strategies throughout the facility targeting adverse</p>	Q 081	<p>projects and implementing those changes as well.</p> <p>Documentation must and will be maintained on these projects and will include the reason or necessity for implementing the project, the measurable data or information gathered and analyzed as well as the implementation of actions to be taken as a result of this data. At regular intervals data will be collected and analyzed to determine if the corrective measures utilized were effective</p> <p>Modifications to the Policy and Procedure manual addressing all components of performance improvement projects will be completed by March 28th. The Governing Body will approve and assign an appropriate data-driven project. An introduction will be available stating the problem prone area to be analyzed, data to be collected and anticipated outcome for performance</p>	

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Q 082	Continued From page 4 patient events and ensure that all staff are familiar with these strategies. This STANDARD is not met as evidenced by: Based on staff interview and review of QAPI documents, it was determined the facility failed to ensure quality indicator data was collected and used to monitor the effectiveness and safety of its services. The ASC also failed to use data to identify opportunities to improve its processes. This prevented the ASC from objectively evaluating its processes and services. Findings include: The only data that was documented in 2012 and 2013 was obtained through patient satisfaction surveys. No objective data had been gathered. No analysis of data was documented. No documentation that data had been used to evaluate processes of care and services was present. The DON was interviewed on 2/20/13 beginning at 11:05 AM. She confirmed no data had been collected beyond the patient satisfaction surveys. She also confirmed no data had been analyzed in relation to processes of care at the ASC.	Q 082	Improvement. This introduction will also be completed and available by March 28 th , 2013. The QAPI Committee will monitor and track the projects. Dr. Dillé, QAPI Director, will be responsible for implementing this plan of correction.	
Q 083	The ASC failed to collect and utilize data. 416.43(d) PERFORMANCE IMPROVEMENT PROJECTS (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.	Q 083		

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Q 083	Continued From page 5 (2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results This STANDARD is not met as evidenced by: Based on staff interview and review of policies and QAPI documents, it was determined the facility failed to ensure performance improvement projects were developed and conducted. This limited the ability of the ASC to evaluate complex processes of care. Findings include: 1. ASC policies did not define performance improvement projects and did not state the ASC would conduct such projects. The DON was interviewed on 2/20/13 beginning at 11:05 AM. She confirmed the QAPI policies did not address performance improvement projects. 2. No performance improvement projects which included the gathering and analysis of data were documented for 2012 and 2013. The DON was interviewed on 2/20/13 beginning at 11:05 AM. She confirmed performance improvement projects utilizing data had not been conducted. The ASC failed to conduct performance improvement projects.	Q 083	Q 084 416.43 (e) GOVERNING BODY RESPONSIBILITIES Although The Governing Body at SIPI has been very active in ensuring that its QAPI program is defined, implemented and maintained by the Ambulatory Surgery Center (ASC) it failed to address the utilization of data collection methods, frequency and details involved in conducting performance improvement projects. Although an active QAPI plan has long been developed, it failed to contain details of "data-driven" projects. The projects developed over the past years have definitely been utilized to involve, change and improve staff performance and patient care processes. Unfortunately, because these were not "data-driven", they fail to provide a measureable improvement or concrete evidence to prove a successful or failed outcome.	
Q 084	416.43(e) GOVERNING BODY RESPONSIBILITIES	Q 084		

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Q 084	<p>Continued From page 6</p> <p>The governing body must ensure that the QAPI program-</p> <p>(1) Is defined, implemented, and maintained by the ASC.</p> <p>(2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness.</p> <p>(3) Specifies data collection methods, frequency, and details.</p> <p>(4) Clearly establishes its expectations for safety.</p> <p>(5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of QAPI documents, it was determined the facility failed to ensure the governing body defined, implemented and maintained a QAPI program that gathered and collected data in order to evaluate processes of care. This resulted in a lack of guidance to staff and limited the ability of the ASC to evaluate its services. Findings include:</p> <p>A plan for QAPI activities including the definition of quality indicators, the utilization of data, and conducting performance improvement projects, was not documented for 2012 and 2013.</p> <p>The physician owner of the ASC was interviewed on 2/20/13 beginning at 3:15 PM. He stated he was in charge of the QAPI program. He confirmed a QAPI plan had not been developed. He confirmed data had not been collected and utilized in 2012 and 2013. He stated no changes had been made to patient care processes in the past year as a result of the utilization of data. He</p>	Q 084	<p>PLAN OF CORRECTION:</p> <p>Modifications will be made to the Governing Body portion of the Policy and Procedure manual to include a detailed plan to ensure it will define and maintain a "data-driven" QAPI project(s) program. This program will address the ASC's priority to utilize quality indicators and utilization of data to improve overall performance and quality of care within the facility. The modifications will ensure the Governing Body will provide the staff with time, information systems and training in order to implement an effective QAPI program. Dr. Dillé, Managing Member, will be responsible for overseeing the implementation of these corrections. These corrections will be completed by March 28, 2013.</p>	

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

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Q 084	Continued From page 7 also stated staff had not received training related to QAPI.	Q 084	Q 181 416.48(a) ADMINISTRATION OF DRUGS	
Q 181	The governing body did not provide direction to staff regarding the development and maintenance of the QAPI program. 416.48(a) ADMINISTRATION OF DRUGS Drugs must be prepared and administered according to established policies and acceptable standards of practice. This STANDARD is not met as evidenced by: Based on staff interview, observation, and review of policies, it was determined the facility failed to ensure policies and procedures were developed to identify loss or diversion of controlled substances. This failure had the potential to result in delays of identification of loss of controlled medications. Findings include: 1. The policy "Scheduled Narcotics," revised 4/10/10 was reviewed. It stated "All narcotic logs will have a continuous count, are maintained by the Director of Nursing and count is witnessed monthly." The policy did not explain how controlled substances would be continuously monitored. The ASC's controlled substance log was reviewed at 4:40 PM on 2/19/13. This log documented the name of controlled medications the ASC supplied in the cabinet (Versed, Fentanyl, Morphine, Meperidine and Promethazine), the amount of medication used or wasted, the date and time the	Q 181	Although SIPI has had an excellent and successful record of tracking stocked scheduled narcotics and medications it is time to change its policy on proper documentation. Since we are a small facility, keeping a running total (confirmed each time a medication is used) and witnessed monthly totals has worked in the past; however, it is time to change these policies to better ensure and maintain accuracy with the medication counts as well as providing a more timely and efficient means of guaranteeing totals are not tampered with. The new policy will detail a change to daily counts of all scheduled narcotics stocked in the ASC in order to better track any discrepancies that may arise. Since the facility also functions as a clinic at assigned times, a separate double lock cabinet will be purchased for scheduled narcotics used by the	

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Q 181	<p>Continued From page 8</p> <p>medication was withdrawn, the patient the medication was used for, the physician's name and the DON's name. The log included documentation to indicate the amounts of the controlled medications in supply had been counted and verified on a monthly basis. The log contained documentation indicating the DON only verified Versed on the days she administered the medication. For example, counts of Versed were documented on 1/15/13, 1/16/13, 1/21/13, and 1/29/13. Counts of the other controlled substances were not conducted on a routine basis. The only documented count of the other controlled substances between 1/15/13 and 2/18/13 occurred on 2/04/13. In addition, the ASC stocked pre-filled Morphine syringes. These were not included on the log.</p> <p>The DON was interviewed at 4:40 PM on 2/19/13. She explained that she documented the amount of Versed she removed and the remaining total of Versed left each day that she administered Versed. She confirmed she completed a count of all controlled medications at the beginning of each month. She stated she did not count all the controlled medications on a daily basis, only the medication she used. The DON was again interviewed on 2/20/13 at 9:05 AM. She stated the pre-filled Morphine syringes were not included in the controlled substance count.</p> <p>The ASC did not ensure controlled substances were counted and verified on a routine basis.</p> <p>2. During a tour of the facility on 2/19/13 at 4:40 PM, the surveyor observed the medication cabinet. The cabinet contained the above mentioned narcotics as well as Lunesta, Hyalgan,</p>	Q 181	<p>clinic. This will enable the Director of Nursing (DON) to be exclusively responsible for all ASC narcotic counts. Although Dr. Dillé will also have access to the knowledge of where the keys will be at all times the DON will be responsible for daily counts and monthly witnessed totals will provide a check system as well.</p> <p>PLAN OF CORRECTION:</p> <p>A second security cabinet has been ordered and delivery is expected the second week of March. This will allow all stocked scheduled medications used in the clinic to be kept separately and keyed differently. Modifications to policies regarding improving the tracking of and securing scheduled narcotics used in the ASC will be developed and implemented as well. These changes will ensure controlled substance used in the ASC will be much more securely monitored. Dr. Dillé, the Managing Member, will be responsible for overseeing the implementation of these changes.</p>	

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Q 181	Continued From page 9 Intermezzo and pro-filled Morphine syringes. The DON was interviewed on 2/20/12 at 9:05 AM. She stated the Lunesta, Hyaigan, Intermezzo and pre-filled Morphine syringes were used by the clinic associated with the ASC. She stated she did not perform counts or verify the amounts of medications used by the clinic. She stated she was the only person who had access to the cabinet while the facility performed procedures, but on days that were for clinic only, the CMA's and PA's had access to the medications inside the cabinet, including narcotics used for the ASC. She agreed that because other staff had access to these medications, this allowed for the possibility of a medication to be missing without her knowledge until she verified at the beginning of the month. She agreed that the current policy and practice of storing ASC and clinic medications together and verifying medications monthly was not an effective system to identify and minimize loss or diversion of all controlled medications. Scheduled medications were not stored or verified to minimize loss or diversion.	Q 181	These corrections will be complete before March 28, 2013 Q 242 INFECTION CONTROL PROGRAM For the past three years, SIPI has based the majority of its Infection Control Policy on guidelines of the Association of Professionals in Infection Control (APIC), a nationally recognized program. SIPI purchased APIC'S Infection Prevention Manual for Ambulatory Surgery Centers and considers it a valuable resource. APIC's email and social network programs commonly used among Infection Preventionist (IP) nationally is monitored and utilized almost daily by SIPI's appointed IP, [REDACTED], RN. Along with this network, [REDACTED], a member of APIC, has had an open relationship with other local IPs and utilizes information from them as well for promoting, creating and updating SIPI's unique and effective Infection Control policies specifically designed	
Q 242	416.51(b) INFECTION CONTROL PROGRAM The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.	Q 242		

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Q 242	Continued From page 10 This STANDARD is not met as evidenced by: Based on staff interview and review of policies, it was determined the facility failed to ensure the infection control program was developed based on nationally recognized guidelines and provided guidance for tracking and investigating infections. This failure prevented the ASC from positively identifying and preventing infections, as well as mitigating the associated risks. Findings include: 1. The ASC failed to identify infections as follows: a. The ASC's policy "Infection Control," revised 4/10/10, was reviewed. It contained the "Infection Control Compliance Plan" which stated "Prevention: Follow-up phone calls the day following procedures are a priority and documented in the 'Plan' portion of the patient's medical record. If there is an unusual response or obvious concern in signs, symptoms or complaint, the note is also forwarded to the medical director for his attention and advice. The medical director may call the patient or the patient may be requested to stop in for an evaluation by the medical director for a precautionary step...If an infection is determined, an additional infection tracking sheet will be submitted to the Infection Control and Quality Control Committees for further review and investigation." The DON was interviewed on 2/20/13 at 10:00 AM. She stated the primary method used to identify post-op (operative) infections was the follow-up phone call done the day after the procedure. She stated that during the follow-up call, the patient was asked about pain and whether there were any concerns or questions. She stated the facility did not ask questions	Q 242	for the demands and needs of this particular facility. She is responsible for developing the majority of the policies and procedures and is diligent in educating and supervising the staff in infection control measures and practices in an ongoing manner. SIPI was not aware of the need to document sources of information used in developing policies. Failure to site nationally recognized sources in the Policy and Procedure manual has now been brought to the ASC's attention and will be remedied by adding credit where applicable. APIC and other pertinent nationally recognized infection control guidelines used in developing protocols will be documented in the Policy and Procedure's Infection Control section where appropriate and will be added as policy changes occur in the future as well. SIPI has an exceptional IP record and prides itself in maintaining this record. It takes its IP responsibilities very seriously and this can be seen	

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Q 242	<p>Continued From page 11</p> <p>specifically related to post-op infections during this phone call, but expected the patient to volunteer this information. She stated that if the ASC was unable to reach the patient, a message was left instructing the patient to call with concerns, but again, no instructions were given specifically related to post-op infections. She stated another possible way to identify post-op infections was during the follow up visit in the clinic. She stated that some patients follow up in the clinic associated with the ASC, but those visits could vary from one week post-op to six weeks post op. She explained that if patients followed up with their referring physician instead of in the clinic, the ASC relied on that physician to inform the ASC if the patient had developed a post-op infection. She stated that there was no formal agreement or procedure for this. She acknowledged there was not a system in place to ensure the ASC was identifying post-op infections.</p> <p>b. The document "DISCHARGE INSTRUCTIONS" was reviewed. The document contained instructions for activity, medications and possible side effects related to the procedure performed. There were no instructions informing the patient of signs and symptoms of a post-op infection or what to do if these symptoms occurred.</p> <p>The DON reviewed this form and was interviewed at 10:00 AM on 2/20/13. She confirmed the "DISCHARGE INSTRUCTIONS" lacked information related to signs and symptoms of infection. She agreed that without instructions related to signs and symptoms of post-op infections, the ASC could not assume the patient</p>	Q 242	<p>by the staff's diligence in its disinfecting and cleanliness as well as other infection prevention and control activities. Although it was stated in the survey that the "primary method used to identify post-op (operative) infections was the follow-up calls done the day after the procedure" that is not an accurate statement. Yes, the day following procedures [REDACTED] is responsible for making the majority of the calls but rarely would this be an accurate indicator since signs or symptoms of infections are not likely to develop within the first 24 hours. During these calls the patients are reminded that if they have any questions or concerns to please call the facility. Many of our patients are scheduled at a later date in either the ASC or the clinic for a follow up appointment; therefore, this would be the facility's major means of tracking a potential infection as well as open communication with the patient's primary care physician. The need to</p>	

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Q 242	<p>Continued From page 12</p> <p>would report these signs and symptoms during a post-op phone call.</p> <p>c. The ASC's policy "Infection Control" stated "Surveillance is defined as a systematic method of collection, consolidation and analysis of data, relating to specific events of infection or disease, followed by information to those who improve outcomes." There was no language in the policy to clarify how surveillance would be conducted, such as what and how data was to be collected and how it was to be analyzed.</p> <p>The policy also contained "Infection Control Surveillance." This section stated "All personnel must provide continuous infection control surveillance measures." It was unclear what this meant or how this was to occur.</p> <p>The DON reviewed the policy and was interviewed at 10:00 on 12/20/13. She confirmed the policy was unclear as to what surveillance meant and how it was to occur. She stated personnel provided continuous infection control surveillance measures by monitoring each other in hand hygiene practices. However, there was no documentation of these activities.</p> <p>The ASC did not have a system for identifying post-op infections.</p> <p>2. The ASC failed to select and implement nationally recognized infection control guidelines as follows:</p> <p>The policy "Infection Control," revised 4/10/10 was reviewed. There was no documentation in the policy to indicate nationally recognized</p>	Q 242	<p>further develop and modify a post-operative infection "surveillance" policy is warranted. In order to ensure and improve on the facility's Infection Control policies and methods overall, some changes have already been made and will continue to be made. SIPI's post-operative discharge instructions have been modified to include an "infection" section informing the patient of signs and symptoms of infection and requesting they call if any of these were to occur. Follow up phone calls will review the need to be aware of monitoring for signs or symptoms as well and reminded to call if any concerns should arise. When this information is provided it will be documented as well in the plan section of the chart.</p> <p>PLAN OF CORRECTION:</p> <p>Changes to the Discharge instructions and information provided during follow up calls concerning awareness of potential signs and symptoms of infection</p>	

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Q 242	Continued From page 13 Infection control guidelines were being used. The DON was interviewed on 2/20/13 at 2:15 PM. She stated the infection control program was based on guidelines from APIC and the CDC. During the interview, she produced information taken from articles and sample tests that were incorporated in the infection control program, but there was no documentation to indicate the source of these materials. She confirmed there was no documentation to indicate the infection control program was based on nationally recognized guidelines. The ASC's infection control program was not based on nationally recognized guidelines.	Q 242	have already been completed and are being implemented. Documentation of recognized resources utilized in developing policies and procedures in the Policy and Procedure manual will be added. Modifications to present policies and procedures in relation to follow up phone calls and infection surveillance protocols to improve or clarify infection control and prevention will be developed. [REDACTED], RN, will be responsible for modifying and/or creating policies and siting sources utilized in the Infection Control Policy(s). [REDACTED] and Dr. Dillé will mutually be responsible for implementing all changes and developing a plan for Infection Surveillance. We feel this plan of correction can be completed by March 28, 2013.	