

COPY



IDAHO DEPARTMENT OF
HEALTH & WELFARE

C.L. "BUTCH" OTTER – Governor
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3232 Elder Street
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May 2, 2012

Teri Paluso, Administrator
IPC Surgical Center, LLC
2841 Juniper Drive
Lewiston, ID 83501

RE: IPC Surgical Center, LLC, Provider #13C0001048

Dear Ms. Paluso:

This is to advise you of the findings of the Medicare survey of IPC Surgical Center, LLC, which was conducted on April 26, 2012.

Enclosed is a Statement of Deficiencies/Plan of Correction Form CMS-2567, listing Medicare deficiencies. In the spaces provided on the right side of each sheet, please provide a Plan of Correction. It is important that your Plan of Correction address each deficiency in the following manner:

An acceptable plan of correction (PoC) 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 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 the Form CMS-2567.

Teri Paluso, Administrator
May 2, 2012
Page 2 of 2

After you have completed your Plan of Correction, return the original to this office by **May 14, 2012**, and keep a copy for your records.

Thank you for the courtesies extended to us during our visit. If you have questions, please call this office at (208) 334-6626.

Sincerely,

Handwritten signature of Karen Dewey RN in black ink.

KAREN DEWEY
Health Facility Surveyor
Non-Long Term Care

Handwritten signature of Nicole Wisenor in black ink.

NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

KD/srm
Enclosures

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

PRINTED: 05/01/2012
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 13C0001048	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 04/26/2012
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NAME OF PROVIDER OR SUPPLIER IPC SURGICAL CENTER, LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 2841 JUNIPER DRIVE LEWISTON, ID 83501
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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
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Q 000	<p>INITIAL COMMENTS</p> <p>The following deficiencies were cited during the recertification survey of your Ambulatory Surgical Center. The surveyors conducting the review were:</p> <p>Karen Dewey RN, BS, HFS, Team Lead Aimee Hastriter RN, BS, HFS Mark Grimes, Supervisor of Facility Fire Safety and Construction Program</p> <p>The following acronyms were used in this report:</p> <p>FDA - Federal Drug Administration HP - History & Physical IV - Intravenous mcg - microgram mg - milligram ml - milliliter NS - Normal Saline OR - Operating Room RN - Registered Nurse</p>	Q 000		
Q 063	<p>416.42(b) & (c) ADMINISTRATION OF ANESTHESIA</p> <p>b) Anesthetics must be administered by only: (1) A qualified anesthesiologist; or (2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in §410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases where a non-physician administers the anesthesia, unless exempted in accordance with paragraph (c) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the</p>	Q 063		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE *Teresa Paluso* TITLE *Administrator* (X6) DATE *5-18-2012*

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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Q 063	<p>Continued From page 1 supervision of an anesthesiologist.</p> <p>(c) State Exemption (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law. (2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview, review of medical records, and observation, it was determined the facility failed to ensure anesthetic medication (Propofol) was administered by appropriately qualified personnel for 4 of 4 patients (Patients #3, #9, #10, and #18) who received an anesthetic as part of conscious sedation during procedures. This had the potential to result in increased risk of complications to patients from anesthesia. Findings include:</p>	Q 063	<p>ADMINISTRATION OF ANESTHESIA:</p> <p>Action: Propofol will only be administered by an anesthesiologist who is presently on staff if the need arises. Propofol will no longer be administered by registered nurses for moderate sedation. This became effective 15 minutes after the Medicare exit interview on 4/26/2012.</p> <p>How the actions will improve the processes that led to the deficiency: The discontinuation of RN's administering Propofol for moderate sedation will put IPC Surgical Center into compliance with the Medicare regulations.</p> <p>Procedure for implementing the acceptable plan of correction: RN's will no longer administer Propofol for moderate sedation. If the need arises, an anesthesiologist on staff will administer propofol.</p> <p>Completion date: 4/26/2012.</p> <p>Monitoring and tracking procedures: The Clinical Nurse Coordinator will notify the Administrator any time Propofol is checked out of the narcotic safe and requested to be given.</p> <p>Title of person responsible for implementing the plan of correction: Teri Paluso, Administrator</p>	

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Q 063	<p>Continued From page 2</p> <p>1. The facility's Conscious Sedation policy, revised 12/2009, stated in section 1.4 "Criteria for Administration of Conscious Sedation" that "Conscious sedation and/or anxiolysis (including: Propofol) will be administered by a physician or a Registered Nurse (RN) and/or Physician Assistant (PA) under the direction of the physician, who have been credentialed and granted privileges by the governing body."</p> <p>However, the manufacturer's medication information insert, "Warnings," dated 1/2009, when used for anesthesia/sedation purposes, Propofol should "be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure." Additionally, in a letter dated 8/11/10, the Director for the Center for Drug Evaluation and Research stated to the American College of Gastroenterology, "the warning [related to Propofol] is warranted and appropriate in light of the significant risks associated with Propofol." Therefore, administration of Propofol required a CRNA, anesthesiologist, or another appropriately trained physician.</p> <p>On 4/25/12 from 10:05 AM to 12:05 PM, Patient #18 was observed having a lumbar epidural steroid injection. The RN in the OR was administering IV conscious sedation, which included Versed 1 mg IV and Propofol 10 mg IV. The physician was in the OR, but was engaged in the procedure. Propofol was observed to be administered by the RN.</p> <p>The RN who administered Propofol to Patient #18</p>	Q 063			

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Q 063	<p>Continued From page 3</p> <p>was interviewed 4/25/12 at 11:10 AM. She stated she had given Propofol, but not until the physician had entered the room.</p> <p>Additionally, the records of Patients #3, #9, and #10 documented Propofol had been administered by the facility's RNs as follows:</p> <ul style="list-style-type: none"> - Patient #3 was a 93 year old female admitted to the facility for a procedure on 3/01/12. The "PROCEDURE/SEDATION RECORD" indicated the RN administered Versed 1 mg IV at 12:20 PM per the facility's standing order. However, the RN also documented the administration of Propofol 30 mg IV at 12:24 PM and Propofol 20 mg IV at 12:30 PM. - Patient #9 was a 36 year old female admitted to the facility for a procedure on 1/25/12. The "PROCEDURE/SEDATION RECORD" indicated the RN administered Versed 3 mg IV at 11:12 AM per the facility's standing order. However, the RN also documented the administration of Propofol 40 mg IV at 11:12 AM and Versed 2 mg IV at 11:14 AM. - Patient #10 was a 75 year old male admitted to the facility for a procedure on 2/08/12. The "PROCEDURE/SEDATION RECORD" indicated the RN administered Propofol 60 mg IV at 12:02 PM, Propofol 30 mg IV at 12:02 PM, Propofol 30 mg IV at 12:06 PM, and Propofol 50 mg IV at 12:15 PM. <p>On 4/25/12 at 11:45 AM, the Clinical Nurse Manager was interviewed. She confirmed the documentation that Propofol was administered by an RN to Patients #3, #9, and #10. She stated</p>	Q 063			

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Q 063	Continued From page 4 the ASC had a conscious sedation privileging process, including competency checks, which all the RNs had completed to be able to administer Propofol. She stated she did not know that RNs could not give Propofol and thought the conscious sedation privileging and competency would allow them to give Propofol just like Versed.	Q 063			
Q 184	The facility failed to ensure Propofol was administered by appropriately qualified personnel in accordance with manufacturer direction and nationally recognized standards. 416.48(a)(3) VERBAL ORDERS Orders given orally for drugs and biologicals must be followed by a written order signed by the prescribing physician. This STANDARD is not met as evidenced by: Based on review of facility policies, medical records, and interview it was determined the facility failed to ensure verbal orders for medications and IV fluids given intra-procedurally were signed by the physician for 9 of 11 sample patients (#2, #3, #4, #7, #9, #10, #11, #12 and #19) who received conscious sedation during procedures. Failure to obtain a physician signature for verbal orders impeded the verification of medication and IV fluid administration per physician order. Findings include: The medical records for Patients #2, #3, #4, #7, #9, #10, #11, #12 and #19 were reviewed. Each medical record contained a "PERI-OPERATIVE	Q 184	VERBAL ORDERS: Action: A signature line was added to the peri-operative record for the physician to sign verbal orders for moderate sedation. How the actions will improve the processes that led to the deficiency: The physician signing the verbal orders for moderate sedation will put IPC Surgical Center into compliance with the Medicare regulations. Procedure for implementing the acceptable plan of correction: Revised Peri-Operative Form to include signature line for physician to sign orders for moderate sedation. RN's complete "chart check" to ensure physician has signed verbal orders. Completion date: 4/27/2012. Monitoring and tracking procedures: We will perform a chart audit of 30 records per quarter to ensure verbal orders for moderate sedation are signed by the physician. Title of person responsible for implementing the plan of correction: Teri Paluso, Administrator		

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Q 184	<p>Continued From page 5</p> <p>RECORD" form. One section of this form was titled, "PROCEDURE/SEDATION RECORD." In this section the RN documented the name, dose, and route of the conscious sedation medication administered and the time it was given.</p> <p>The facility policy, "Conscious Sedation and Reversal Standing Orders," last reviewed by the facility July 2011, contained standing orders which included the following:</p> <ul style="list-style-type: none"> - Versed 1-3 mg IV initial dose - Fentanyl 50 mcg IV initial dose - Propofol (Not given until physician enters the room). <p>According to the standing orders, only the initial dose of Versed or Fentanyl, at the specific dosages noted, was authorized and signed for by the physician. Subsequent doses of medication and IV fluids used during the procedure were additional verbal orders and therefore required a signature from the prescribing physician.</p> <p>The medical records did not contain a physician signature for the individual orders of medications and IV fluids administered during the procedures as follows:</p> <p>a. Patient #3 was a 93 year old female admitted to the facility for a procedure on 3/01/12. The "PROCEDURE/SEDATION RECORD" indicated the RN administered Versed 1 mg IV at 12:20 PM per the facility's standing order. However, the RN also documented the administration of Propofol 30 mg IV at 12:24 PM and Propofol 20 mg IV at 12:30 PM. In addition, the RN documented Patient #3 received 250 mls of NS during the</p>	Q 184			

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Q 184	<p>Continued From page 6</p> <p>procedure. The medical record did not contain a physician signature for the verbal orders of Propofol and NS administration.</p> <p>b. Patient #7 was a 51 year old female admitted to the facility for a procedure on 1/30/12. The "PROCEDURE/SEDATION RECORD" indicated the RN administered Versed 2 mg and Fentanyl 50 mcg IV at 11:24 AM per the facility's standing order. However, the RN also documented the administration of an additional 1 mg of Versed and 50 mcg of Fentanyl IV at 11:32 AM. The medical record did not contain a physician signature for the verbal orders of the additional medications administered.</p> <p>c. Patient #11 was 27 year old male admitted to the facility for a procedure on 2/16/12. The "PROCEDURE/SEDATION RECORD" indicated the RN administered Versed 1 mg and Fentanyl 50 mcg IV at 9:25 AM per the facility's standing order. However, the RN also documented the administration of an additional 1 mg of Versed and 50 mcg of Fentanyl IV at 9:30 AM. The medical record did not contain a physician signature for the verbal orders of the additional medications administered.</p> <p>d. Patient #10 was a 75 year old male admitted to the facility for a procedure on 2/08/12. The "PROCEDURE/SEDATION RECORD" indicated the RN administered Propofol 60 mg IV at 12:02 PM, Propofol 30 mg IV at 12:02 PM, Propofol 30 mg IV at 12:06 PM, and Propofol 50 mg IV at 12:15 PM. The RN also documented Patient #10 received 400 ml of NS and was on 2 liters per minute of supplemental oxygen. The medical record did not contain a physician signature for</p>	Q 184			

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Q 184	<p>Continued From page 7 these verbal orders.</p> <p>e. Patient #12 was a 74 year old female admitted to the facility for a procedure on 2/27/12. The "PROCEDURE/SEDATION RECORD" indicated the RN administered Versed 1 mg and Fentanyl 50 mcg IV at 8:32 AM per the facility's standing order. However, the RN also documented the administration of an additional 0.5 mg of Versed at 8:37 AM, 0.5 mg of Versed at 8:42 AM, and 50 mcg of Fentanyl at 9:10 AM. The RN also documented Patient #12 received 600 ml of NS and supplemental oxygen at 5 liters per minute via blowby using a mask. The medical record did not contain a physician signature for these verbal orders.</p> <p>f. Patient #2 was an 80 year old female admitted to the facility for a procedure on 4/18/12. The "PROCEDURE/SEDATION RECORD" indicated the RN administered Versed 1 mg IV at 11:20 AM per the facility's standing order. However, the RN also documented the administration of Versed 1 mg IV at 11:30 AM, and Versed 1 mg IV at 11:50 AM. The medical record did not contain a physician signature for the verbal orders of the additional Versed doses.</p> <p>g. Patient #4 was a 66 year old female admitted to the facility for a procedure on 3/19/12. The "PROCEDURE/SEDATION RECORD" indicated the RN administered Versed 2 mg IV at 10:33 AM per the facility's standing order. However, the RN also documented the administration of Fentanyl 25 mcg IV at 10:33 AM. The medical record did not contain a physician signature for the verbal order of Fentanyl.</p>	Q 184			

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Q 184	<p>Continued From page 8</p> <p>h. Patient #9 was a 36 year old female admitted to the facility for a procedure on 1/25/12. The "PROCEDURE/SEDATION RECORD" indicated the RN administered Versed 3 mg IV at 11:12 AM per the facility's standing order. However, the RN also documented the administration of Propofol 40 mg IV at 11:12 AM and Versed 2 mg IV at 11:14 AM. The medical record did not contain a physician signature for the verbal orders for Propofol and the second dose of Versed.</p> <p>i. Patient #19 was a 57 year old male admitted to the facility for a procedure on 4/05/12. The "PROCEDURE/SEDATION RECORD" indicated the RN administered Fentanyl 50 mcg IV at 11:05 AM per the facility's standing order. However, the RN also documented the administration of NS 250 ml and supplemental oxygen 6 liters per minute by mask. The record did not contain a physician signature for the verbal orders for the NS and the oxygen.</p> <p>The Clinical Nurse Manager was interviewed on 4/25/12 at 2:16 PM. She confirmed that the initial dose of sedative medication was administered under the guidance of the standing orders. She stated that additional medications and IV fluids administered were done via verbal orders from the physician during the procedure. She reviewed the medical records for Patients #2, #3, #4, #7, #9, #10, #11, #12 and #19. She confirmed that the verbal orders for medications and IV fluids administered beyond the initial dose of Fentanyl and Versed were not signed by the prescribing physician.</p> <p>Verbal orders for medications and IV fluids given intra-procedurally were not signed by the</p>	Q 184			

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Q 184 Q 262	Continued From page 9 physician. 416.52(a)(2) PRE-SURGICAL ASSESSMENT Upon admission, each patient must have a pre-surgical assessment completed by a physician or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy that includes, at a minimum, an updated medical record entry documenting an examination for any changes in the patient's condition since completion of the most recently documented medical history and physical assessment, including documentation of any allergies to drugs and biologicals. This STANDARD is not met as evidenced by: Based on review of medical records and interview it was determined the facility failed to ensure a physician examined patients prior to procedures for 6 of 20 patients (#1, #5, #8, #13, #16, and #20) whose medical records were reviewed. Failure to perform this pre-surgical assessment had the potential to impact patient safety during and after the procedure. Findings include: 1. Medical records for Patients #1 (admitted on 4/23/12), #5 (admitted on 2/15/12), #8 (admitted on 2/02/12), #13 (admitted on 3/28/12), #16 (admitted on 4/19/12), and #20 (admitted on 8/25/11) did not include documentation of a physical examination (such as listening to heart and lungs with a stethoscope) prior to procedures completed without conscious sedation. The Clinical Nurse Manager was interviewed on	Q 184 Q 262	PRE-SURGICAL ASSESSMENT: Action: Heart and lung examination will be completed by the physician on each patient prior to the procedure. How the actions will improve the processes that led to the deficiency: The physician performing the heart and lung examination on all patients (not just patients receiving moderate sedation) will put IPC Surgical Center into compliance with the Medicare regulations. Procedure for implementing the acceptable plan of correction: Education was provided to the physicians during the Medicare exit interview on 4/26/2012. Physicians immediately began performing heart and lung examination on all patients within 15 minutes of the exit interview. Completion date: 4/26/2012. Monitoring and tracking procedures: We will perform a chart audit of 30 records per quarter to ensure heart and lung examination is being performed and documented by the physician. Title of person responsible for implementing the plan of correction: Teri Paluso, Administrator	

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OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 13C0001048	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 04/26/2012
NAME OF PROVIDER OR SUPPLIER IPC SURGICAL CENTER, LLC			STREET ADDRESS, CITY, STATE, ZIP CODE 2841 JUNIPER DRIVE LEWISTON, ID 83501		
(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 262	<p>Continued From page 10</p> <p>4/25/12 at 2:16 PM. She reviewed the medical records for Patients #1, #5, #13, and #20 and confirmed that the documentation present indicated no physical assessment had been completed prior to the planned procedures.</p> <p>Additionally, the Physician who performed Patient #16's procedure was interviewed on 4/25/12 at 2:08 PM. He stated he did not routinely complete a physical assessment, which would include listening to a patient's heart and lungs, if the patient did not receive sedation. He stated if he thought the patient needed a complete examination, even if there was no sedation involved, he would perform the assessment but may not document it.</p> <p>A second Physician, who performed Patient #8's procedure, was interviewed on 4/25/12 at 1:45 PM. He stated he agreed he did not complete a physical assessment because Patient #8 did not receive sedation.</p> <p>The Administrator was interviewed on 4/25/12 at 1:45 PM. She stated she did not realize a complete physical assessment was required when no sedation was given.</p> <p>The facility did not ensure physicians performed complete physical assessments prior to procedures.</p>	Q 262			

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IDAHO DEPARTMENT OF
HEALTH & WELFARE

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May 2, 2012

Teri Paluso, Administrator
IPC Surgical Center, LLC
2841 Juniper Drive
Lewiston, ID 83501

Provider #13C0001048

Dear Ms. Paluso:

On **April 26, 2012**, a complaint survey was conducted at Ipc Surgical Center, Llc. The complaint allegations, findings, and conclusions are as follows:

Complaint #ID00004772

Allegation #1: A patient was not informed of the details of the procedure to be performed including the risks and benefits, and subsequent negative side effects of the procedure were not incorporated into the medical record.

Finding #1: An unannounced complaint investigation was conducted 4/23/12 through 4/26/12. Medical records and complaints/grievances were reviewed and patients were interviewed with the following results:

A list of discharged patients treated in the surgery center was reviewed. From this list twenty medical records were reviewed. Each medical record contained documentation of a signed informed consent. The records contained documentation that the physician discussed the risks and benefits of the procedures with patients. Each medical record contained documentation of medication allergies and the patients' allergic responses to those medications.

Two current patients were interviewed. Each patient stated they felt the physician and nursing staff had done a thorough job of explaining the risks and benefits of the procedures and that all of their questions had been answered.

Teri Paluso, Administrator
May 2, 2012
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The complaint/grievance documentation was reviewed. There was no documentation of a patient concern related to lack of knowledge related to a procedure or negative side effects sustained as a result of a procedure.

It could not be determined that a patient was not aware of the details of the procedure to be performed and medical records contained documentation of allergies and intolerances. Therefore, the allegation was unsubstantiated and no deficient practice was identified.

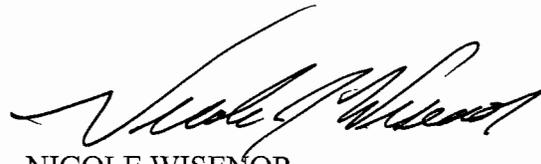
Conclusion: Unsubstantiated. Lack of sufficient evidence.

As none of the allegations were substantiated, no response is necessary. Thank you for the courtesies and assistance extended to us during our visit.

Sincerely,

Handwritten signature of Karen Dewey in black ink, including the initials 'KD' at the end.

KAREN DEWEY
Health Facility Surveyor
Non-Long Term Care

Handwritten signature of Nicole Wisenor in black ink.

NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

KD/srm