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YORKVILLE ENDOSCOPY LLC	201 EAST 93TH STREET, 2ND FLOOR NEW YORK, NY 10128

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Q 000	INITIAL COMMENTS STATE FACILITY ID #9448 OPERATING CERTIFICATE #7001300R COMPLAINT # NY00152029 NOTE: THE DEFICIENCIES BELOW ARE CITED AS A RESULT OF A FEDERAL ALLEGATION SURVEY CONDUCTED ON 09/02, 09/03, 09/04 AND 09/05/2014 IN ACCORDANCE WITH 42 CFR PART 416, SUBPARTS A THROUGH C, TO ASSESS COMPLIANCE WITH CONDITIONS OF COVERAGE FOR AMBULATORY SURGICAL CENTERS (ASCs). Based on the review of medical records, documents, policies and procedures and interviews, it was determined that the facility failed to ensure that patient care services are provided in a manner that protects the health and safety of all patients. This deficiency was noted in Patient (PT) #1. Specifically, it was determined that the facility failed to: (1) Have a process in place to assure that only authorized personnel are permitted in the procedure room. (2) Have an effective process in place to assure that only credentialed physicians can perform procedures. (3) Ensure that informed consent is obtained for all procedures that will be performed and. (4) Ensure a "Time Out" (a pre-procedure protocol for verification of the correct person,	Q 000		

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

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procedure and site) was called to confirm each procedure to be performed.

As a result of the significant findings that were identified which compromised patient safety, an Immediate Jeopardy (IJ) was declared on 09/03/2014 at approximately 3:15 PM.

In response, the facility submitted a corrective action plan to the surveyor on 09/03/2014 at approximately 6:30 PM, indicating that they: will develop and/or revise policies and procedures to govern the practice of admitting visitors and observers to the facility, credentialing and privileging, code of ethics, informed consent and the "Time-Out" procedure; and will provide comprehensive training to staff on these policies, training on empowerment and code of ethics.

The surveyor made on-site visits on 09/04 and 09/05/2014 and confirmed that the facility implemented the corrective actions. The surveyor:
(a) Reviewed and validated the new/revised policies with Staff #4 and Staff #6, and the policies were fully accepted by the surveyor on 09/05/2014 at approximately 4:20 PM.
(b) Confirmed implementation of staff education training and observed training provided by Staff #6 on 09/04/2014 at approximately 1:30 PM.
(c) Validated the Mandatory Training packet utilized for staff training with Staff #4 and Staff #6.
(d) Validated the Attendance Records of staff training provided from 09/04/2014 through 09/05/2014 at 6:30 AM. Review of the records showed that the training was completed by 92% of the Full Time RNs (Registered Nurses), Anesthesiologists, Technicians and the Business Office Staff, and 66% of the Credentialed

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Physicians. This was verified by Staff #4 and Staff #6 and Staff #6 stated the training will continue for the per diem employees.
(e) Verified the implementation of the process for identification of unauthorized staff; presence of the "Visitors Log" at the front desk; list of credentialed physicians maintained at the front desk. This process was verified with Staff #4 and Staff #6.
(f) Verified with the Clinical Coordinator, the process to ensure that only approved staff are in the procedure room.
(g) Confirmed through staffing pattern for 09/05/2014 and Monday, 09/08/2014, that only physicians and staff who had received this training were scheduled to provide care at the facility. The staffing pattern was confirmed with Staff #6 who stated the mandatory training will continue prior to work on 09/08/2014. A written statement of certification was also obtained from Staff #3 and Staff #4, stating, "No employee or medical staff member will be permitted to enter a procedure room until they have undergone this training.
(h) Observed the implementation of the revised "Time Out" on 09/05/2014, during the procedure for two patients at approximately 12:45 PM and at 1:10 PM. Two added elements were implemented and the team (a) verified the consent was signed for the procedure to be performed, (b) confirmed only assigned and authorized (the surveyor) staff were present in the procedure room.

ON 09/05/2014, AT 6:10 PM, THE SURVEYOR DECLARED THAT THE IMMEDIATE JEOPARDY (IJ) HAD BEEN REMOVED WHEN THE

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Q 000	Continued From page 3 MEASURES IMPLEMENTED BY THE FACILITY WERE ACCEPTED BY THE NEW YORK STATE DEPARTMENT OF HEALTH. DESPITE THE ABATEMENT OF THE IMMEDIATE JEOPARDY (IJ) SITUATION, THE FACILITY REMAINED OUT OF COMPLIANCE BECAUSE NOT ALL STAFF HAVE BEEN TRAINED. THE CONDITION(S) FOR COVERAGE NOT IN COMPLIANCE INCLUDE: 416.41 Condition for Coverage: Governing Body and Management 416.42 Condition for Coverage: Surgical Services 416.45 Condition for Coverage: Medical Staff 416.50 Condition: Patient Rights THE PLAN OF CORRECTION, HOWEVER, MUST RELATE TO THE CARE OF ALL PATIENTS AND PREVENT SUCH OCCURRENCES IN THE FUTURE. INTENDED COMPLETION DATES AND THE MECHANISM(S) ESTABLISHED TO ASSURE ONGOING COMPLIANCE MUST BE INCLUDED.	Q 000		
Q 040	416.41 GOVERNING BODY AND MANAGEMENT The ASC must have a governing body that assumes full legal responsibility for determining, implementing,and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.	Q 040		

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Q 040	Continued From page 4 This CONDITION is not met as evidenced by: Based on interviews, review of medical record and other documents, it was determined that the Governing Body and Management failed to provide adequate oversight and monitoring to ensure compliance with the facility's policies for providing patient care services and that patient care services are provided in a manner that protects the health and safety of patients. This finding was noted in 1 of 12 patient records reviewed (Patient #1). Findings include: 1. The facility failed to ensure that the staff complied with the Surgical Services policy and procedures for Physician Privilege and "Time Out" procedure. See Tag Q 0060 2. The facility failed to ensure that the staff complied with its Medical Staff Bylaws. See Tag Q 0120 3. The facility failed to ensure that the staff complied with the Conditions of Coverage: Patient Rights for Informed Consent and Privacy. See Tag Q 0219-Condition: Patient Rights.	Q 040		
Q 060	416.42 SURGICAL SERVICES Surgical procedures must be performed in a safe	Q 060		

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manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC

This CONDITION is not met as evidenced by:
Based on interviews, the review of medical records and other documents it was determined the facility failed to ensure that surgical services are provided in a manner that protects the health and safety of patients. Specifically, the facility failed to ensure (1) that surgical services were provided by a qualified physician granted privilege at the facility; (2) the implementation of the facility's policy and procedure on "Time Out" to assure patient's safety; (3) continuous assessment and treatment of patient's medical condition in accordance with generally accepted standards for medical practice. This finding was noted in 1 of 12 patient records reviewed (Patient #1).

Findings include:

1. Patient #1 is an 81-year-old female who presented to facility on 8/28/14 for a scheduled EGD (Esophagogastroduodenoscopy), a procedure in which a thin scope with a light and camera at its tip is used to look inside the area between the throat and upper intestines. The patient's past medical history included Chronic Reflux disease (a chronic condition that involves mucous membrane damage caused by stomach acid coming up from the stomach into the esophagus).

Staff #1, patient's Endoscopist notes in the Pathology Requisition form that was untimed,

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indicated that "endoscopy was indicated for the patient to evaluate the pathophysiology (The functional changes resulting from disease or injury) and extent of tissue injury associated with GERD (gastroesophageal reflux disease)". However, the patient's medical record indicated the patient underwent a Nasolaryngoscopy (A diagnostic procedure that examines the nasal passageways and the area between the cavity of the mouth and the throat to the muscular passage connecting the mouth with the stomach) prior to the EGD and another Nasolaryngoscopy after the EGD was completed.

In a Post-Procedure Note documented by Staff #2, the patient's Anesthesiologist on 8/28/14 at "2:36.37 PM", she notes that two Nasolaryngoscopies were performed by an ENT (Ear Nose and Throat) surgeon. The ENT surgeon was identified by her name in another note that was hand written by Staff #3.

At interview with Staff # 3, Interim Medical Director of the facility on 9/2/14 at 3:50 PM, he stated the ENT surgeon that performed the Nasolaryngoscopy was not a member of the Medical Staff and was not privileged at the facility.

Review of the facility's Medical Staff Bylaws, reviewed on 9/3/14, indicates that "Medical Staff" means licensed physician that has been appointed to the Medical Staff in accordance with the facility's Bylaws. Article II, section 2 (a) of the Medical Staff Bylaws states "Medical Staff membership shall be extended only to physicians who can document their background, experience, training, competence, adherence to professional ethics, good reputation, and ability to work with others, with sufficient adequacy to assure the

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Medical Executive Committee that any patient treated by them in the Center will be given medical care at an acceptable level of quality and efficiency, shall be qualified for membership on the Medical Staff".

Further interview was conducted with Staff #4, Vice President, Clinical Operations on 9/2/14 at 4:00 PM; she stated the facility has no information about the ENT surgeon. She confirmed the ENT surgeon is not privileged at the facility and she is not in any of the categories of Medical Staff established by the Medical Staff Bylaws. Staff #4 stated that the ENT surgeon was not an Active, Provisional, Teaching, or Consulting Medical Staff at the Endoscopy Center.

However, on 8/28/14, the ENT surgeon who is not privileged at the facility performed Nasolaryngoscopy on Patient #1 in the presence of the facility's Medical Director - Staff #1, an Anesthesiologist - Staff #2, and an Endoscopy Technician - Staff #5.

At interview with Endoscopy Technician, Staff #5 on 9/3/14 at 2:05 PM, she stated she was informed prior to the start of the procedure that Patient #1 will be coming in with her personal doctor. She stated the ENT surgeon walked into the procedure room escorted by Staff #1. Staff #5 stated the ENT surgeon was gowned and was holding a suitcase. Staff #5 reported that Staff #1 had requested for an extra table so the ENT surgeon can set up her suitcase. Staff #5 stated that after the "Time Out" was announced for the EGD and sedation was administered by Staff #2, the ENT surgeon announced, "I will go first". The ENT surgeon performed a laryngoscopy before

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Q 060	Continued From page 8 the EGD was done. She stated that after the EGD was completed on 9/28/14 at 9:28 AM, by Staff #1, the ENT surgeon went in again with a laryngoscope and was there for a minute or two. Staff #5 stated that Staff #1 and Staff #2 did not object to the ENT surgeon performing the laryngoscopy. At interview with Staff #2 on 9/2/14 at 3:15 PM, she stated that she met the ENT surgeon for the first time in the procedure room on 8/28/14, prior to the patient's procedure that began at 9:00 AM. 2. The Intra-Procedure Note for Patient #1 indicated a "Time Out" was performed on 8/28/14 prior to the scheduled EGD procedure. The "Time Out" was announced by the Endoscopy Technician on 8/28/14 at 9:04.36 AM, and not by the Anesthesiologist as indicated in the policy. The facility's "Time Out" policy and procedure (Policy #6.20), effective January 2013, was reviewed on 9/3/14. The policy notes that prior to the start of a procedure, the patient is asked to state the procedure to which he/she has consented. This information is documented on the procedure record. "The anesthesiologist will announce a "Time Out" and the physician, anesthesiologist and RN and or endoscopy technologist will stop what they are doing to reconfirm the patient's identification, procedure, site and side, supplies, equipment and diagnostic imaging." The policy further notes that all parties will sign off on the procedure record and record time accordingly.	Q 060		

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The Time Out checklist, also referred to as "Safe Surgery Checklist", documented by the Endoscopy Technician - Staff #5, was not accurately completed. The Endoscopy Technician notes the following: the patient has confirmed identity using two identifiers; patient has confirmed the procedure and the consent form is correct and complete; the team members in the procedure room have identified themselves and their role; and the team members in the procedure room verbally verified the patient and procedure.

The review of the medical record shows that not all members of the procedure team were identified in the Procedure Note and the role of each team member was not clearly understood by all team members. The team, prior to the procedure, failed to verify procedures to be performed and the indication for each procedure. Not all parties involved in the patient's procedure signed off on the procedure record and record time in accordance with the policy.

Post-Procedure Note by Staff #2 on 8/28/14 at 2:36.37 PM, revealed that, prior to the Endoscopy procedure, the patient had a transnasal intubation with a direct laryngoscope by an ENT surgeon. The ENT surgeon performed another transnasal intubation with a laryngoscope immediately following the completion of Endoscopy by Staff #1.

The ENT surgeon was noted in the patient's medical record as one of the referring physicians, but not as a member of the procedure team. The presence of the ENT surgeon in the procedure room as well as her involvement in the procedures performed was not documented in

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the "Time Out" checklist or in the medical record. In a note written by Staff #2 on 8/28/14 at 2:36 PM, she indicated the presence of the ENT surgeon and her involvement in the procedure room.

At interview with Staff #2 on 9/2/14 at 3:15 PM, she stated she was willing to discuss the case, but she has been advised by her legal representative not to discuss the case at this time.

At interview with Endoscopy Technician, Staff #5 on 9/3/14 at 2:05 PM, she stated the ENT surgeon performed a Laryngoscopy for Patient #1 that was aborted because the ENT surgeon stated she could not see very well what she was trying to view. She stated that Staff #1 proceeded with the EGD and when it was completed at 9:28 AM, the ENT surgeon went in again with a laryngoscope and was there for a minute or two. She stated the laryngoscope was withdrawn at 9:30 AM. Staff #5 confirmed there was no separate "Time Out" announced for the initial Nasolaryngoscopy conducted prior to the EGD and the second Nasolaryngoscopy after the EGD.

3. The review of the Procedure Notes and Cardiac Resuscitation Records for Patient #1 revealed the physicians in charge of the care of the patient failed to identify deteriorating vital signs and provide timely intervention during the procedure on 8/28/14. Abnormal vital signs as well as abnormal values of peripheral capillary (the smallest of a body's blood vessels located away from the heart, such as, in the arms, hands, legs and feet) oxygen saturation (a term referring to the concentration of oxygen in the blood - SpO2 - normal levels are considered 95 to 100

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percent), and End-tidal carbon dioxide (ETCO2 - concentration of carbon dioxide in the expired air; normal value is 35 to 45 millimeters Mercury (mmHg) were not addressed.

Pre procedure vital signs on 8/28/14 at 8:44.06 AM were as follows:
Blood Pressure (BP) 118/80, Pulse 62 Regular, Respirations 16, Temperature (Temp.) 97.2 Fahrenheit, SPO2 100%.

Intra-procedure vital signs were as follows:
9:12.49 AM - BP 117/60, Pulse 71, SpO2 92%
9:16.13 AM - BP 92/54, Pulse 56, Respirations 16, SpO2 94%, ETCO2 26
9:21:42 AM - BP 89/44, Pulse 54, Respirations 17, SpO2 97%, ETCO2 19
9:26.36 AM - BP 84/40, Pulse 47, SpO2 92%

The Cardiac Arrest Record indicated that resuscitation of the patient was initiated two minutes later at 9:28 AM.

However, at interview with Staff #5, on 9/3/14 at 2:15 AM, she stated that following the EGD scope withdrawal at 9:28 AM, the ENT doctor proceeded to do another Nasolaryngoscopy. The Endoscopy Technician reported, "ENT doctor was in there for a minute or two before the removal of the laryngoscope at 9:30 AM. Vital signs recorded at 9:30:04 notes a blood pressure of 85/49, no pulse recorded, and oxygen saturation was at 92%.
In the addendum by the Anesthesiologist, Staff #2 at 2:36 PM, she notes that the patient maintained saturation at approximately 90% during Laryngoscopy. In another note hand written by Staff #2, she explained that oxygen saturation was maintained with a combination of jaw thrust and increase in oxygen flow to 5 Liters/min (liters

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Q 060	Continued From page 12 per minute). There was conflicting information in the medical record regarding the time resuscitation was initiated and the overall management of the patient during the code (situations requiring cardiopulmonary resuscitation). There were two code records in the patient's medical record. One of the record titled Cardiac Arrest Record indicated the patient went into cardiac arrested at 9:28 AM and cardiopulmonary resuscitation was initiated at 9:30 AM. This record notes that the first set of medications, Epinephrine 1 milligram (mg) and Atropine 1 mg were administered at 9:38 AM. The second code record titled Endoscopy Code Blue Record noted the patient had a pulse and was in ventricular tachycardia (V-tach or VT - a type of rapid heart beat, that starts in the bottom chambers of the heart, called the ventricles, the main pumping chambers of the heart) at 9:28 AM. It was documented that assisted ventilation and chest compression were initiated at 9:28 AM. However, there was no indication that the ventricular tachycardia with presence of pulse was immediately treated in accordance with Advanced Cardiac Life Support. Instead, the code record notes that Epinephrine 1 mg and Atropine 1 mg were administered to the patient at 9:28 AM. The patient was successfully resuscitated at 10:00 AM and transferred to a hospital at 10:04 AM for further management. The patient expired at the hospital on 9/4/14 at 1:15 PM.	Q 060		
Q 061	416.42(a)(1) ANESTHETIC RISK AND	Q 061		

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Q 061	Continued From page 13 EVALUATION A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. This STANDARD is not met as evidenced by: Based on interview, the review of medical record and other documents, it was determined that staff failed to follow standards of practice for the use of moderate and deep sedation. This finding was noted in 1 of 12 patient records reviewed (Patient #1). Findings include: Review of the medical record for Patient #1 noted the patient's body weight was not recorded and utilized as part of the pre-assessment of the patient prior to the administration of medication for sedation. The policy titled "Use of Moderate and Deep Sedation, effective January 2013, notes that during the pre-assessment of a patient, the anesthesia provider and the registered nurse will review the following on assessment: (a) vitals, (b) weight, (c) current medications, (d) past medical history, (e) current medical history, (f) current medication, (g) allergies, and (h) prior problems with anesthesia. At interview with Staff #8 on 9/30/14 at 3:30 PM, he stated that patient's body weight is very critical for the pre anesthesia assessment especially for medication calculation.	Q 061		
Q 120	416.45 MEDICAL STAFF	Q 120		

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Q 120	Continued From page 14 The medical staff of the ASC must be accountable to the governing body. This CONDITION is not met as evidenced by: Based on interviews, review of medical record and other documents, it was determined the facility's Medical Staff failed to comply with Medical Staff Bylaws to assure patient's safety. Specifically, Medical Staff members failed to assure that only physicians who have been credentialed and appointed as members of the Medical Staff at the facility, could provide and supervise the care of patients. this finding was noted in 1 of 12 patient records reviewed (Patient #1). Findings include: 1. The facility did not ensure that Patient #1 was cared for only by physicians that have been granted privilege in accordance with the facility's Bylaws. See Q -0060	Q 120		
Q 162	416.47(b) FORM AND CONTENT OF RECORD The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following: (1) Patient identification. (2) Significant medical history and results of physical examination. (3) Pre-operative diagnostic studies (entered before surgery), if performed. (4) Findings and techniques of the operation,	Q 162		

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Q 162	Continued From page 15 including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body. (5) Any allergies and abnormal drug reactions. (6) Entries related to anesthesia administration. (7) Documentation of properly executed informed patient consent. (8) Discharge diagnosis. This STANDARD is not met as evidenced by: Based on interview and the review of medical records, it was determined the facility failed to ensure that medical records are accurate and complete. This finding was noted in 1 of 12 records reviewed (Patient #1). Findings include: The review of medical record for Patient #1 on 9/2/14 revealed the following: 1. The medical record lacked an informed consent for each procedure performed. There was no consent obtained from Patient #1 for a Nasolaryngoscopy performed on 8/28/14. See Tag Q 219. 2. The medical record lacked documentation of patient's body weight. See Tag Q 061. 3. The dose of Propofol (a short acting sedative hypnotic used in short procedures and minor surgeries) administered to the patient for sedation was inconsistently documented in the medical record.	Q 162		

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Q 162	Continued From page 16	Q 162		

The Medication Administration Record notes a total dose of 300 milligram of Propofol was given to Patient #1 during the procedures she underwent at the facility. Propofol 100 milligram at 9:21.45 AM, 100 milligram at 9:21.46 AM, AM, 50 milligram at 9:21.48 AM and 50 milligram at 9:21.50.

However, an addendum by Staff #2 - Anesthesiologist, on 8/28/14 at 2:36 PM, notes there is a mistake in the Propofol log; the correct dose given was 120 milligram and not the 300 milligram documented in the Medication Administration Record.

At interview with Staff #2 on 9/2/14 at 3:00 PM, she stated she was advised by her legal counsel to defer interviews, but she emphasized to the survey team that she gave Propofol 120 milligram. She stated the 300 milligram of Propofol recorded in the Medication Administration Record was a mistake. She explained she double clicked on Propofol 100 milligram and that is the reason for the double dose recorded in the Medication Administration Record. She added that after the administration of Propofol 100 milligram , she gave an additional dose of 20 milligram and not the two doses of Propofol 50 milligram recorded in the Medication Administration Record on 8/28/14 at 9:21.48 AM and 9:21.50 AM.

4. Two cardiac resuscitation records noted in the medical record for Patient #1 contained conflicting information regarding the time resuscitation was initiated and the overall management of the patient during the code.

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Q 162	Continued From page 17 One record titled Cardiac Arrest Record indicated the patient went into cardiac arrested on 8/28/14 at 9:28 AM and cardiopulmonary resuscitation was initiated at 9:30 AM. This record notes that the first set of medications, Epinephrine 1 milligram and Atropine 1 milligram were administered at 9:38 AM. However, the second code record titled Endoscopy Code Blue Record noted the patient had a pulse and was in ventricular tachycardia at 9:28 AM. It was documented that assisted ventilation and chest compression were initiated at 9:28 AM. The code record notes that Epinephrine 1 milligram and Atropine 1 milligram were administered to the patient at 9:28 AM. In this record the medications are indicated as being administered 10 minutes earlier than what is indicated in the initial Cardiac Arrest Record.	Q 162		
Q 219	416.50 PATIENT RIGHTS Condition for Coverage - Patient Rights The ASC must inform the patient or the patient's representative or surrogate of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable. This CONDITION is not met as evidenced by: Based on interviews, review of medical records and other documents, the facility failed to ensure patients are afforded their rights. Specifically, the facility failed to ensure (1) that informed consent is obtained prior to the start of each procedure	Q 219		

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Q 219	Continued From page 18 performed at the facility; (2) the implementation of its policy for the protection of patient's privacy. These findings were noted in 1 of 12 patient records reviewed (Patient #1). See Q -0229 and Q-231.	Q 219		
Q 229	416.50(e)(1)(iii) EXERCISE OF RIGHTS - INFORMED CONSENT [[(1) The patient has the right to the following:] (iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed. This STANDARD is not met as evidenced by: Based on interviews, the review of medical record and other documents, it was determined the facility failed to obtain an informed consent for procedure to be performed. Specifically, an informed consent was not documented for laryngoscopies performed on patient #1 on 8/28/14. This finding was noted in 1 of 12 records reviewed (Patient #1). Findings include: Patient #1, an 81-year-old female presented to the facility on 8/28/14 for a scheduled EGD. On the day of the procedure (on 8/28/14), the patient signed a consent for "Upper Endoscopy (EGD), with possible biopsy/possible polypectomy, possible dilation of esophagus". The consent was obtained by the Endoscopist - Staff #1. The physician notes in the "Pathology Requisition form" that endoscopy was indicated for the patient to evaluate the pathophysiology and extent of tissue injury associated with GERD (gastroesophageal reflux disease).	Q 229		

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Q 229	Continued From page 19 The anesthesia consent signed by the patient on 8/28/14 at 8:50 AM indicated the patient consented for an Endoscopic procedure under Monitored Anesthesia Care (MAC) and risks/benefits had been explained to the patient. The consent was obtained by Staff #2, the Anesthesiologist. Staff #2 in her Pre-Anesthesia Assessment certifies that the patient has confirmed the procedure and the consent form is correct and complete. However, Post- Procedure Note by Staff #2 on 8/28/14 at 2:36.37 PM, revealed that prior to the Endoscopy procedure, the patient had a transnasal intubation with a direct laryngoscope by an ENT surgeon. The ENT surgeon performed another transnasal intubation with a laryncoscope immediately following the completion of Endoscopy by Staff #1. The facility's policy titled "Informed Consent', last revised 9/5/14 notes procedures will be performed only upon written consent of the patient or his legal representative, except in emergencies. In the event of an emergency, all life saving measures, in the opinion of the physician, will be performed to save a patient's life. The record shall contain a statement to that effect signed by the physician, patient or her/his designee and witness. There was no documentation of an informed consent for the Laryngoscopy performed by the ENT surgeon. There was no documentation that the patient received information necessary to make an informed decision prior to the procedure. The indication for the procedure as well as risks/benefits of the procedure was not	Q 229		

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Q 229	Continued From page 20 explained to the patient and noted in the medical record. At interview with Staff #4 on 9/3/14 at 13:00, she validated that there was no informed consent for the Laryngoscopy performed by the ENT surgeon.	Q 229		
Q 231	416.50(f)(1) PRIVACY The patient has the right to - (1) Personal privacy This STANDARD is not met as evidenced by: Based on interview, the review of medical record and other documents, it was determined the facility failed to implement its policy to assure patients' rights to privacy. This finding was noted in 1 of 12 patient records reviewed (Patient #1). Findings include: The five-page hand written note by Staff #2 was provided to the survey team by Staff #7 in the presence of Staff #2 on 9/2/14 at 3:15 AM. Staff #2 stated the hand written note was part of the medical record for Patient #1. Staff #2 notes that during a second laryngoscopy performed by the ENT surgeon, "he" (Staff #1) "proceeded to take pictures of the surgeon and the patient with his cell phone". Medical record documentation indicates that the patient was sedated at the time of the photograph. At interview with Staff #2 on 9/2/14 at 3:15 PM, she stated she was willing to discuss the case, but she has been advised by her legal representative not to discuss the case at this time.	Q 231		

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Q 231	Continued From page 21 On 9/4/14 at approximately 2:30 PM, Staff #5 was interviewed, she said, "Staff #1 used a cell phone to take pictures of Patient #1 and the ENT surgeon during the second laryngoscopy". Staff #5 reported that "Staff #1 said maybe Patient #1 would like to see this in the recovery area". The facility's "Cell Phone Policy" last revised January 2014 notes that "personal Cell phones shall not be used in any patient care areas as this can compromise patient safety." It further notes that "personal cell phones shall be turned off or set to silent or vibrate mode while you are at work, and should be kept in your locker or purse. If there is a special circumstance of a limited duration that requires you to need your cell phone turned on, please speak with your manager, and gain prior approval." There was no indication the facility's Cell Phone Policy was enforced by staff members. There was no documentation of prior consent by Patient #1 authorizing her photographs to be obtained by facility's staff members during the procedure.	Q 231		