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A 000	INITIAL COMMENTS A federal/state complaint investigation was conducted at this facility subsequent to the Department receiving telephone notification on 9/19/08 from the hospital ' s Chief Executive officer, regarding a wrong side arthroscopic knee surgery. Three conditions of participation (Medical Services, Nursing Services and Surgical Services) were reviewed. Federal and State deficiencies were cited relative to Surgical Services.	A 000		
A 940	482.51 SURGICAL SERVICES If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered. This CONDITION is not met as evidenced by: The occurrence of a never event (e.g., wrong-sided surgery) and the failure to meet standards of practice related to A 951, A955 and A 959. A review of the medical record for patient ID #1 and interviews with staff indicated that this is a 60 year old admitted to the Ambulatory Surgery Center (ASC) in the Fain building on 9/19/08 for an elective left knee arthroscopy. An MRI (Magnetic Resonance Imaging) confirmed a meniscal tear of the left knee. The PreProcedure Verification Checklist, (PPVC) is a tool designed and used by the Hospital to verify that certain steps have been completed prior to surgery. The PPVC has the patient	A 940		

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

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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information stamped in the upper right hand corner, a place for the date and procedure to be performed followed by five sections, two to be completed by nurses prior to the patient entering the OR suite, one by the anesthesia provider and one by the surgeon. The fifth section is for " time out " to verify information, prior to surgery, to be completed by the nurse based on checks with the surgeon, procedure nurse and anesthesia provider. Each of the sections at a minimum require the following steps/information to be verified: patient name, patient date of birth, written informed consent, correct procedure, " site/side/level per policy " , and when applicable " marking per policy " .

This PPVC also includes a " time out " performed between the attending physician, procedure RN and anesthesia provider when applicable. This "time out" list includes the following items: 'correct patient', 'correct procedure', 'correct site/side/level per policy', 'correct patient position', 'correct x-rays available' and 'when applicable' 'site marking visible', 'correct implants available', and 'special equipment available.'

The "Intraop Clinical Documentation" indicates that the procedure is a left knee arthroscopy, partial medial menisectomy. The patient is transported from the holding area by stretcher, accompanied by the nurse and CRNA (Certified Registered Nurse Anesthetist), to Surgicenter Room 4 at 0812. Documentation indicates "Low profile leg holder applied directly below padded tourniquet on right thigh, fob (foot of bed) dropped. Safety strap over chest, arms secured bilaterally on padded arm boards". Procedure Nurse prepped right leg with Chloraprep from the

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leg holder to ankle. General anesthesia was administered at 0822.

Time out is documented at 0832. The "Time Out" section checklist signed by the procedure nurse at 0832 indicates correct patient, correct procedure; correct site/side/level of the procedure per policy, correct patient position, and site marking is visible. Surgery commenced at 0832. The surgeon began the procedure and there was no indication from the surgical team that the wrong side had been operated on including at the end when the incorrect knee (right knee) was bandaged.

Surgery stop time is documented at 0900, and a dry sterile dressing with an ace wrap was applied to the right knee and at this time no one was aware the wrong knee had been operated on. The nurse and the anesthetist transported the patent to the Surgicenter recovery room from Room 4. At 0935, the nurse's notes indicate that the patient is awake and stating that the "wrong knee was operated on. Patient is upset and crying".

On 9/19/08, the patient requested a repair of the left knee meniscal tear and was taken to surgery for a second time at 12:05PM.

This wrong side surgery for ID#1 triggers a condition of participation level deficiency

We reviewed the medical record for ID#1, interviewed staff involved with patient ID#1 ' s care as well as other OR staff, reviewed hospital policies including the surgical care policy/procedure, "Universal Protocol to Prevent Wrong Site, Wrong Procedure and Wrong Person

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A 940	Continued From page 3 surgery", hospital administration (e.g. CEO, risk management, etc), reviewed medical forms and checklists, medical records related to procedures and operations in the hospital. This revealed implementation failures not only for patient ID #'1 that resulted in a "never event" (e.g. wrong sided surgery) but also failure to adhere to standards A 951, A 955 and A959. Our findings found both technical related problems and system and organizational culture related problems that were either directly related to or that could have lead to a wrong-sided surgery or medical error. These included: - Failure to follow hospital policy to prevent wrong site, wrong procedure and wrong person surgery o Failure to verify the site marking is visible in surgical field during the time out process. o Failure to include information on the preprocedure verification checklist on the procedure/surgery type and site. o Failure to verify during the time out that the site that is marked and draped is consistent with any imaging test results. o Inconsistency between hospital policy, pre-procedure verification checklist and " white board " utilized during the time out. o Failure of the primary surgeon to take a leadership role in the time-out re-verification procedure o Confusion amongst staff as to what " site verification " means and what it should entail during the time out. Some staff verify the correct site by confirming that the site had been marked in preoperative area and others verify the correct site by viewing and confirming that the surgical site has a visible mark. - Failure to verify information during the time	A 940		

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A 940	Continued From page 4 out (instead they all agreed that the information about the procedure was correct (e.g. administrative verification of information related to surgery rather than actual re-verification or primary source verification of the surgery type and site). o Administrative verification during the time out was done by the team as a whole or by individuals who had performed each activity that was to be verified rather than having a "double check" or redundant re-verification (e.g. view the mark on the patient immediately before initiating surgery, verifying the site by checking available imaging study results, reviewing the consent form, etc). - Failure to routinely confirm with another person the marked site as they prepare the surgical site (e.g. " draping and prepping of site "). - Lack of appropriate equipment (i.e. indelible pen to mark surgical sites that can wash off during surgical site preparation). - Lack of routine date & time information on consent forms - Lack of an adequate system and culture of near miss reporting Details related to these findings and additional failures that were found in the reviews of 9 of 22 other patient medical records are referred to in A 951, A 955 and A959 herein.	A 940		
A 951	482.51(b) OPERATING ROOM POLICIES Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.	A 951		

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This STANDARD is not met as evidenced by:
Based on a visual inspection of the operating rooms, medical record reviews, patient care policies, and interviews with both staff involved with patient ID#1 and interviews with other staff and hospital administration (e.g. CEO, risk manager), and observations of time outs during surgery, it was determined that the hospital failed to ensure that a surgical care policy & procedure: "Universal Protocol to Prevent Wrong Site, Wrong Procedure and Wrong Person Surgery", was implemented for patient ID #'s 1, 11, and 12.

Findings are as follows:

The hospital policy entitled "Universal Protocol to Prevent Wrong Site, Wrong Procedure and Wrong Person Surgery", states the following:

In the policy section:

"In Compliance with the Joint Commission Patient Safety Standards for universal protocol, it is a policy of The Miriam Hospital to identify and verify procedures, including site, side, and levels if applicable for all patients who will undergo surgery or an invasive procedure requiring written informed consent."

"Surgical/Procedural Site verification requires a standard procedure with multiple checks in the system to minimize the risk of surgery/procedure on the wrong patient or body part".

In the Purpose section, it states:

"Surgical/Procedural Site verification requires a standard procedure with multiple checks in the system to minimize the risk of surgery/procedure

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A 951	Continued From page 6 on the wrong patient or body part" In Section II, Preoperative Area/Prep-procedure Prior to sedation, it states: The Attending Physician is responsible for "Marking for laterality/level " and that the "Mark is visible after prepping and draping". In Section V. it states: "Immediately prior to the start of the procedure a 'Time Out" will be completed." This section states that the Procedural RN is responsible for the execution of time out with "Active communication between all members of the operative/procedural team (attending physician, procedure RN and when applicable anesthesia) to confirm the following: Visibility of marking within operative/procedural field (if applicable)". Although the PPVC for ID#1 has an area to indicate the date and procedure to be done, there is no evidence of this being completed on either the first surgery done on the right (incorrect) knee or the second surgery done later the same day on the left (correct) knee. In addition, the Circulating Nurse signed the "time out" section on the PPVC form with the incorrect date, (9/18/08) instead of 9/19/08. Additionally, on 9/22/08 during an interview with the Circulating Nurse, indicated the "time out" section of the PPVC form was not completed during the time out. The Circulating Nurse stated the "time out" section of the PPVC form was completed at the desk next to the computer in the operating room. The Circulating Nurse completed the "time out" section by drawing a	A 951		

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single line through all the boxes, which includes " site marking visible". This also included a line through " correct implants available " that did not apply to this surgery. In addition, the documented time on the PPVC reflects the exact time the pause was done and the surgery began rather than the later time that the nurse completed the form.

A review of the PPVC for the 2nd surgical procedure revealed no evidence that the procedure to be performed or the date was included anywhere on the checklist. Additionally, under the ' time out " section a different circulating nurse from the first case drew a single line through all the steps to be verified rather than individually checking each step. This also included a line through "correct implants available" that did not apply to this surgery. This single line was also done by the procedure nurse in the pre-procedure area prior to taking the patient back to the operating room and included the line passing through the box " correct implants available. "

During a tour of the Ambulatory Surgical Center (ASC) area on 9/22/08 at10: 45AM, the surveyor observed a white board, which is located on the wall in the Operating Room (OR) next to a computer desk. The white board functions as a Perioperative Checklist ("white board") to verify information during the time out. The "white board" includes the date, patient name, date-of-birth, medical record number, procedure, patient position, surgeons, anesthesia, circulator, scrub and "other" . Areas to be verified include: patient identification, allergies, consent signed history and physical signed within seven days, site verification, antibiotics given, DVT protocol,

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beta Blockers, implants, special equipment, radiological exams and blood product ABO compatibility. Although the white board includes all of the above, there is no area of the board for the visualization of the site marking as outlined in hospital policy. Additionally, during an interview with the surgeon, the surgeon stated there was no x-ray to view. However, there was an available MRI available in the operating room, and it is unclear if the MRI was checked.

During the time out, the circulating nurse utilizes the Perioperative Checklist - "white board" which is located on the wall in the Operating Room (OR) next to a computer desk rather than the PPVC that is part of the permanent medical record and included in the hospital policy. The "white board" is used to verify information during the time out. Although the "white board" includes all of the above, there is no area of the board for the visualization of the site marking or x-rays/imaging availability, as outlined in hospital policy and on the PPVC. During an interview with hospital staff, they indicated that the hospital "Time out" Policy does not include the use of the "white board" .

During an interview on 9/20/08 at 8:10AM with the physician ' s assistant (PA), the PA stated an imaging disc was set up in the operating room. However, it is unclear if the images were checked to verify site location during the time out. This lack of checking the imaging films reflects a lack of understanding of the use of imaging results as another source of information to verify the correct procedure and site during the time out.

A review of the clinical record for patient ID #1 indicates an admission to the ASC (Ambulatory Surgical Center) on 9/19/08 for a scheduled left

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knee arthroscopy. The PPVC completed by the Preprocedure Nurse, the Procedure Nurse, and the Anesthetist has a check mark next to the item "marking per policy". The policy describes how and who should perform the site marking. The surgeon describes marking the patients left knee in the pre-procedure area before the patient was taken into the operating room.

During an interview on 9/22/08 at 2:35 PM the Circulating Nurse stated that after briefly checking the patient's identification, the surgery plan was confirmed. The Circulating Nurse stated the site was identified by reviewing the completed informed consent, and the history and physical. The Circulating Nurse verified the site to be prepped by looking at the marking made by the physician in the pre procedure area, before bringing the patient into the operating room. They also all checked the box on the PPVC " site/side/level per policy " . However, a review of the hospital policy could not locate a description of what is meant by " site/side/level per policy. "

The CRNA and the Circulating Nurse brought the patient into the room and assisted the patient onto the table. The anesthesia induction was started. The Circulating Nurse applied a thigh tourniquet and leg holder, looked at the "white board" in the room, and looked at the patient. The Circulating Nurse was standing at the foot of the table (that the patient was laying on), and the patient's right side was lined up with her left side. The Circulating Nurse dropped the foot of the table so that the patient could be pulled forward to position the leg. The physician assistant (PA) entered the room at that time and assisted in pulling the patient up on the table. The nurse then continued without the physician assistant,

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A 951	Continued From page 10 applied the tourniquet, and prepped the right leg. The Circulating Nurse admitted not looking for the mark on the leg. The Circulating Nurse could not explain the failure to look for the mark in this instance. During an interview with the Scrub Nurse, the nurse indicated that the Chloroprep is usually used in prepping surgical areas, and that the ink used in site markings has been noted to wash off with prepping in the past. In addition the mark can sometimes be hard to visualize with darker skin. This is one reason provided as to why the actual surgical site was not visualized to verify the correct site was marked prior to initiating surgery. Although the scrub technician, and others interviewed, were aware that the marking of a surgical site may wash off during preparation of the site, there is no evidence of any such reports to risk management or to other administrative staff regarding the washing off of a surgical site mark during a the prep. The washing off of the marked site represents a near miss but none of the staff recognized it as such. During an interview with the Attending Physician on 9/22/08 at 1:25 PM, the physician indicated that prior to surgery, they had visited the patient in the holding area, reviewed the surgical consent form and the history and physical, and then proceeded to mark a "Yes" with an indelible marker one inch above the patient's left patella, with patient agreement with the correct site being marked. The surgeon gowned and gloved before entering the room. The Circulating Nurse called a time out. The surgeon further stated that the circulating nurse announced the time out and proceeded to review the list on the "white board".	A 951		

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The hospital policy entitled "Universal Protocol to Prevent Wrong Site, Wrong Procedure and Wrong Person Surgery" states Under Section II " Preoperative Area/Preprocedure - prior to sedation " : the attending physician is responsible for "marking for laterality/level and that the "mark is visible after prepping and draping." The RI Board of Medical Licensure has long established that the attending physician is responsible for site, side, patient and surgery verification immediately prior to starting surgery. The surgeon did mark the site himself. However, although the above policy/protocol was in effect at the time of this wrong-sided surgery, the physician reported focusing on verifying that the antibiotics had been given and failed to focus on site verification by looking at the patient ' s knee. The circulating nurse did call for site verification, but the physician does not recall exactly what was said. The surgeon did not look for the site marking, and does not recall if the nurse asked that the team verify the site marking by looking at the knee.

During the time out, the team agreed with the site marking read from the "white board" . As a result of the above, the right (and incorrect) leg, which had been prepped and draped, was operated on, although no mark was visibleor verified.

During an interview on 9/22/08 at 12:45PM with the surgical Technician, the technician indicated that when it came to site verification, the circulating nurse did not ask for the marking at the site to be verified, (i.e., to look at the surgical site to verify a visible mark on the skin). Instead during the request for site verification, the team agreed with the information that was on the " white board " during the time out.

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A recheck of the primary source for the information on the "whiteboard" was not done. Each individual checklist was not verified which is the intent and purpose of the time out as part of having multiple checks in the system. There is no "primary source" verification of the items on the "white board" during the time out (i.e., recheck the consent, imaging results, etc). Thus, mistakes made by individuals and incorrectly recorded on the "white board" will not be detected during the time out procedure.

Interviews with staff confirmed that a designated second person to visually check the site marking is not routinely performed. The surgeon indicated that circulating nurses have different styles, and some do ask about the visible markings and others do not. These comments reflect a lack of recognition that the attending physician is responsible for checking the mark is visible prior to surgery. In addition, these comments reflect a lack of recognition that the different styles and inconsistent checks of a visible marking immediately prior to surgery represent a "near miss" . This lack of appreciation of near misses was reflected by other team member and nurse comments coupled with the review of all near miss reports to the hospital (see above).

The Circulating Nurse called out stating, "Can we do a pause please?" Using the "white board" in the room, the patient was identified by name, date-of-birth, medical record number, and the procedure and site were called out. The team confirmed the "white board" information related to allergies, consent was identified as signed for the specific procedure, history and physical and site verification. The Circulating Nurse stated that visual inspection of the site marking was not

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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
A 951	Continued From page 13	A 951		

verified. The Circulating Nurse indicated they identified the site by calling out the procedure and site/side that was scheduled, according to the information available on the "white board". The operating room team verified that the information read from the "white board" during time out, however, they did not verify the site marking. When the procedure was completed, the patient was brought to recovery and as of this time no one on the surgical team nor recovery room staff noted that the surgery had occurred on the wrong leg.

This "white board" information does not reflect the hospital policy relative to the visibility of the site marking. On the ' time out " section of the PPVC form the circulating nurse indicated the site marking was visible by drawing a line through the this box as well as the box for correct implant which was not applicable to this surgery. During an interview on 9/22/08 at 2:20PM a 3rd year surgical resident, indicated that the patient was already on the table positioned with the tourniquet on, but not draped. The resident went out to scrub, and came back to find the patient prepped and draped. The surgical resident gowned and gloved, and went over to mark out the sites where the incisions need to be made for the arthroscope. The resident stated that nothing triggered him regarding "no visualization of the mark by the surgeon." When asked if they looked for the site markings before marking the knee for the arthrosope, the surgical resident responded, "I did not, and I regret that."

Nonetheless, the surgical resident admitted there was no visual verification of the site marking during the time out. The time out was done, and everything on the white board was read. The

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	410012	A. BUILDING ______ B. WING ______	C 09/25/2008

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A 951	Continued From page 14 surgical resident stated that staff has different interpretations of site verification, and circulating nurses have their own style. Staff admits that the indelible pen used in site markings often washes off or fades during the prep so that it is sometimes not visible in the surgical field during time outs. During subsequent interviews on 9/22/08 from 12:45 PM through 2:35 PM with additional members of the surgical team (which included the Scrub Nurse, and the CNRA), they also confirmed that the verification of the visibility of the site marking was not done in the Surgicenter Room 4 at any time prior to the surgery, or during the time out. This is because "site verification" is not defined in practice by the staff as meaning an actual visual verification of the marking at the surgical site. During interviews on 9/24/08 between 1:15PM and 3:00PM six of eight circulating nurses both in outpatient surgery and in the Main OR indicated that they are the only people in the OR that verify the correct surgical site. When asked to further explain what they meant by their statements, they stated they are responsible for site verification. However, they do not necessarily look for the mark before the surgeon begins the procedure, they ask for site verification. Upon further questioning, the circulating nurses indicated that at times the scrub nurse might also verify site verification. When asked by the surveyor if the circulating nurse asks everyone in the OR if they can see the mark, they stated that this question is not asked and therefore everyone is not looking for the mark. Only one person performs each check and the physician is not routinely asked if they can see the mark during the time out.	A 951		

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We also conducted a further review of compliance with the hospital policy for procedures performed outside the operating room under hospital policy Section VI, "Procedures Performed Outside of the Operating Room." This section of the policy states under "Eligibility: This applies to all patients undergoing any invasive procedure exposing them to any more than minimal risk, whether or not moderate sedation may be required. This covers all such procedures that are performed outside the Operating Room or other areas designated for specific invasive procedures included, but not limited to: bedside, Critical Care units, Emergency Department and other ambulatory settings in this hospital."

The policy also states: " Time Out: The person performing the procedure will pause to double check that all information about the patient and the intended procedure is documented in the medical record and in agreement with physical and/or other diagnostic findings. Following active verification of the information, the physician or designee and the nurse will sign the Immediate Preprocedure "time out" section on the Bedside Procedure Note attesting to that fact."

In addition to patient ID#1, eight Bedside Procedure Notes for 7 patients were reviewed. Three of these eight revealed that the bedside note for ID #11, and two bedside notes for ID #12, did not have evidence that the nurse had verified the time out process as reflected by no RN signature as required in the "time out" section of the note, per hospital policy. Additionally, during observation by administrative personnel of all time out procedures in the operating room on the next day of elective surgery following the wrong

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A 951	Continued From page 16 site surgery, a miscommunication involving the surgeon and the surgical team occurred during a time out. This incident raises issues involving the communication between surgeons and operating room nurses during the prepping of patients and during the time out process.	A 951		
A 955	482.51(b)(2) INFORMED CONSENT A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies. This STANDARD is not met as evidenced by: Informed consent form for surgery for patient ID # 1 revealed the informed consent was incomplete as it lacked the time the consent was obtained. Based on record review and staff interviews, it was determined that the hospital failed to properly execute the informed consent form for not only patient ID#1 but for 3 of 10 additional patients (ID#'s 3, 5, 6) related to the time consent is obtained. A review of the operative informed consent forms for patient ID #'s 1, 3, 5 and 6 revealed that the informed consents did not contain the time that the consent was obtained, as required for properly executed inform consents. During an interview on 9/25/08 at 2:15 PM with the Risk Manager, they could not produce evidence that the reviewed informed consents were complete, as required.	A 955		
A 959	482.51(b)(6) OPERATIVE REPORT An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.	A 959		

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A 959	Continued From page 17 This STANDARD is not met as evidenced by: The final operative report for patient ID#1 revealed incomplete required information related to notation of time of surgery. Based on record review and staff interviews, it was determined that the hospital failed to include the times of the surgical procedures in the dictated surgeon's descriptive operative report following surgery for 7 of 7 patients reviewed (ID #'s 1, 2, 3, 4, 5, 6, and 7). A review of the operative reports for patient ID #'s 1, 2, 3, 4, 5, 6, and 7 revealed that these reports did not include the times of surgery as required. During an interview on 9/25/08 at 2:15 PM with the Risk Managers, they could not produce evidence that the reviewed operative reports were complete, as required.	A 959		