



*Protecting, Maintaining and Improving the Health of Minnesotans*

Office of Health Facility Complaints  
Public Report

Rochester Methodist Hospital  
201 West Center Street  
Rochester, MN 55902

Case # H0061005

June 13, 2008

By: Sue Jackson, Assistant Director

A substantial allegation survey was initiated on May 22, 2008, related to a complaint of a possible violation of the Conditions of Participation for hospitals participating in Medicare. The complaint is:

The facility does not require patients' written consent for procedures.

Conclusion:

**Substantiated** as it relates to a violation of the Conditions of Participation for hospitals participating in Medicare, specifically the Condition of Surgical Services at CFR 482.51. Due to the hospital's failure to obtain patients' written informed consent, federal deficiencies are issued at A940, the Condition of Surgical Services, and at standard A955 for informed consent.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  240061	(X2) MULTIPLE CONSTRUCTION A. Building _____ B. Wing _____	(X3) DATE SURVEY COMPLETED  C 05/22/02008
NAME OF PROVIDER OR SUPPLIER  ROCHESTER METHODIST HOSPITAL			STREET ADDRESS, CITY, STATE, ZIP CODE 201 WEST CENTER STREET ROCHESTER, MN 55002	
(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 000	INITIAL COMMENTS  Surveyor: 03015 A substantial allegation survey was conducted on May 21 & 22, 2008 in connection with complaint #H0061005. A violation was substantiated and the following deficiencies are issued: 482.24(c)(2)(v) CONTENT OF RECORD – INFORMED CONSENT	A 000		
A466	[All records must document the following, as appropriate:] Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.  This STANDARD is not met as evidenced by: Surveyor: 0301 5 Based on interview, record and policy review the hospital failed to obtain a properly executed consent form for surgical or other invasive procedures. See A 0955 482.51 SURGICAL SERVICES	A 466	<b>482.24 (c) (2)(v) A 466 – CONTENT OF THE RECORD – INFORMED CONSENT</b> Our policy "PR.12 Informed Consent and Medical-Decision Making" will be revised to require a signed informed consent form for specified procedures. The informed consent form will supplement existing policy and practice requiring a discussion with the patient and a clinical note documenting that informed consent was obtained. The form will be scanned into the medical record. When scanning is not feasible prior to the procedure, the paper copy will accompany the patient to the procedure. The policy will be revised, communicated, and implemented throughout Mayo Clinic Rochester, including both hospitals and the clinic.  The policy will be implemented in two phases. The first phase will include all surgeries performed in the operating suites, and the second phase will include other procedures as specified in the policy. Phase one will be implemented by August 11, 2008, and phase two will be implemented in fourth quarter 2008. The Health Information Policy and Compliance Committee will oversee implementation and ensure ongoing compliance through medical record review audits and follow-up as appropriate.	Phase 1 08/11/2008  Phase 2 4thQ2008
A 940	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: Surveyor: 0301 5	A 940	<b>482.51 A 940 – SURGICAL SERVICES</b>  See above text for 482.24 (c) (2)(v) A 466. The same informed consent form and process will used by all practices to ensure that services in outpatient surgical services are consistent with inpatient care.	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVES SIGNATURE *Sydney Frederick* TITLE *Hospital Administrator* (X6) DATE *7/9/2008*  
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 finding as 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 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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A 940	Continued from page 1 Based on interview, record and policy review the hospital failed to obtain a properly executed consent form for surgical or other invasive procedures. See A 0955.	A 940		
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: Surveyor: 0301 5 Based on interview, record and policy review the hospital failed to obtain a properly executed consent form for 12 out of 12 patients (#1-9, and transplant recipients P-1, L-1 & PK-1) who had surgical or other invasive procedures. Findings include:  The hospital's policy "Informed Consent and Medical Decision Making" last approved 6/28/05 by the Clinical Practice Committee did not require written patient consent forms prior to surgery or other invasive procedures. There was no medical staff protocol that outlined what specific information was to be shared with patients when seeking an informed consent for the procedure(s). A review of patient medical records revealed that the physician documentation of the content of the informed consent process varied widely.  Although the medical staff made notations in the medical record that they provided the patient or their representative with the risks, benefits and alternatives of the surgical procedures there was	A 955	482.51(b)(2) A955 – INFORMED CONSENT  See above text 482.24 (c) (2)(v) A 466. The same informed consent form and process will be used by all practices to ensure a standard process.	

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A 955	Continued From page 2 no evidence of a written consent form signed by the patient/representative in 12 out of 12 patients (#1-9, and transplant recipients P-1, L-1 & PK-1). Findings include:  Four of the twelve records reviewed were those of hospital inpatients who were interviewed regarding the informed consent process. All four inpatients interviewed who had undergone recent surgical procedures indicated that they had been apprised of the risks, benefits and alternatives to the surgery but either did not sign or did not remember signing a consent form.  A summary for the four inpatient cases (#s 1 - 4) reviewed is as follows:  A review of patient #1's medical record revealed the patient was admitted on 4/22/08 and underwent three surgeries. The patient interviewed on 5/22/08 at 5:00 PM indicated the pre-operative risks and benefits were explained as well as the procedure. The patient indicated they had given verbal permission but did not recall signing an informed consent.  A review of patient #1's medical record revealed the patient underwent an abdominal exploration with lysis of adhesions on 5/20/08. The "Pre-Operative Exam" performed on 4/21/08 under the "Informed Consent" section, the surgeon documented the following: "Discussed risks, goals, alternatives, advance directives , and necessity of other members of the team participating in the procedure with the patient and parent. The patient and parent had a chance to have any questions about this procedure answered, understand(s) and wish(es) to proceed. The patient consented to the possibility	A 955			

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A 955	<p>Continued From page 3 of a blood transfusion." There was no evidence of a consent form signed by patient #1 or the parent. This was verified by the nursing management staff present during the record review on 5/22/08.</p> <p>A review of patient #2's medical record revealed the patient underwent extensive abdominal surgery on 5/16/08 that included a cholecystectomy, lymphadenectomy, hepaticojejunostomy and bile duct resection. Patient #2 when interviewed on 5/22/08 at 4:30 PM, indicated that the surgeon gave him complete information before he left for surgery and he understood the risks of the surgery. The patient first thought he had signed something but then said he didn't sign anything, (consent).</p> <p>In a "Preoperative Report" dated 4/24/08, for patient #2 the surgeon dictated: "Goals, risks, complications, and alternatives inclusive of transfusions and advance directive discussed with patient and family. Team aspects of medical care discussed. Patient's questions answered. Patient wishes to proceed on the 16th of May. Patient Education: Appears ready to understand and learn from our discussion. No apparent learning barriers were identified from our verbal interactions. Explained diagnosis and treatment plan; patient appears to understand the content of our discussion. Informed Consent: Discussed the risks, benefits, and alternatives of the procedure and possible blood transfusion. Discussed advance directives and the necessity of other members of the healthcare team participating in the procedure. All questions answered and consent given." There was no evidence of a consent form signed by patient #2.</p>	A 955		

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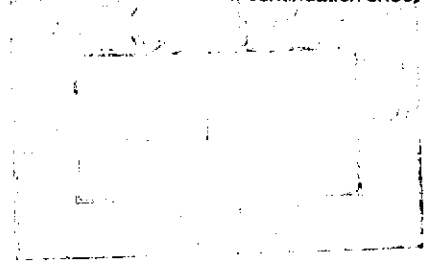
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A 955	<p>Continued From page 4</p> <p>A review of patient #3's medical record revealed the patient underwent a laparoscopic appendectomy and partial cecectomy on 5/20/08. The patient when interviewed on 5/22/08 at 5:05 PM reported she was told what to expect and that she was well informed by the surgeon. Patient #3 did not remember signing a written consent form.</p> <p>A review of patient #3 record revealed a pre-operative note dated 5/19/08 that documented: "Informed Consent Discussed the risks, benefits, alternatives, advance directives, and the necessity of other members of the healthcare team participating in the procedure. All questions answered and consent given." There was no evidence of a consent form signed by patient #3.</p> <p>A review of patient #4's medical record revealed the patient had a mastectomy with lymph node dissection and immediate breast reconstruction on 5/20/08. Patient #4 was interviewed on 5/22/08 between 4:30 and 5:00 PM. Patient #4 indicated that she signed a consent for photographs but did not sign a consent for the surgery. Patient #4 indicated that the physician discussed the general risks and options.</p> <p>A review of patient #4's medical record revealed the surgeon dictated a report of his discussion with patient #4 and the patient's family in a pre-operative history and physical dictated on 5/19/08 which stated: "Discussed with Mrs _____ in the presence of her husband, daughter, and close friend her diagnosis with an invasive breast tumor of the right breast that is clinically node negative." The report went on to detail a discussion of the extent of the disease, choices of total mastectomy vs lumpectomy and rationale,</p>	A 955			

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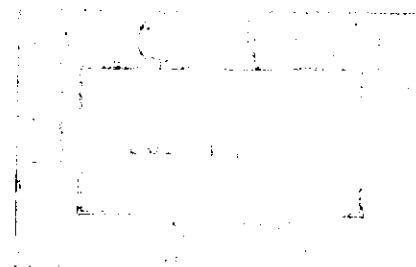
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A 955	<p>Continued From page 5</p> <p>benefits of chemotherapy , timing of reconstructive surgery and pros and cons of the timing, extent of the resection and possible length of a scar, nodal evaluation with lymph node biopsy with radioactive colloid injection, possible need to proceed to right axillary lymph node dissection, and possible need for second operation pending pathological findings. The surgeon outlined the specific plans for the patient to meet with Medical Oncology to gain more information about neoadjuvant chemotherapy . The surgeon, under "Patient Education" , stated: "Appears ready to understand and learn from our discussion. No apparent learning barriers were identified from our verbal interactions. Explained diagnosis and treatment plan; patient appears to understand the content of our discussion." The surgeon finalized the report with: "Informed Consent Discussed the risks, benefits, and alternatives of the procedure and of possible blood transfusion. Discussed advance directives and the necessity of other members of the healthcare team participating in the procedure. All questions answered and consent given." There was no evidence of a consent form signed by patient #4.</p> <p>A review of closed medical records (# 5 - 9) revealed all five patients had surgical procedures. In each of the five medical records reviewed there was a notation by the physician that "informed consent" had been given. There was no evidence of a consent form signed by the patients in any of the 5 patient records reviewed. This was confirmed by nurse managers and quality management personnel present during the record reviews the morning of 5/22/08 from 8:15 to 9:15 AM . The following is a summary of the surgical procedures for patient #s 5-9 and what the</p>	A 955		



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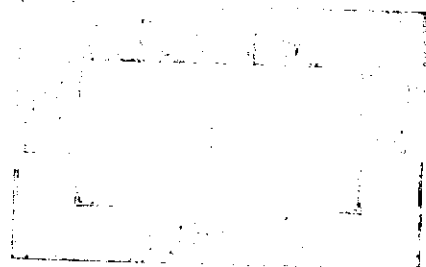
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A 955	<p>Continued From page 6</p> <p>physician documented as being discussed under "informed consent".</p> <p>A review of patient #5's medical record revealed the patient underwent a sigmoid resection with end-to-end anastomosis and bilateral salpingectomy on 5/8/08. Patient #5's "Exam/Report" of 4/23/08 revealed the physician documented the following : "Informed Consent - Discussed the risks, benefits, alternatives, advance directives and the necessity of other members of the healthcare team participating in the procedure. All questions answered and consent given." There was no evidence of a consent form signed by patient #5.</p> <p>A review of patient #6's medical record revealed the patient, (a minor), had a lumbar puncture performed on 1/31/08. Under the "Preprocedure information" the physician documented the following in patient #6's medical record: "Discussed the risks, goals, alternatives and necessity of other members of the team participating in the procedure with parent. The parent had a chance to have any questions about this procedure answered, understand(s) and wish(es) to proceed." There was no evidence of a consent form signed by the parent of patient #6.</p> <p>A review of patient #7's medical record revealed patient #7 underwent a sigmoid resection, abdominal hysterectomy and bilateral salpingo-oophorectomy along with splenic flexure mobilization on 5/7/08. On the 4/24/08 "Exam/Report" the physician documented: "Discussed the risks, benefits, and alternatives of the procedure and of possible blood transfusion. Discussed the necessity of other members of the healthcare team participating in the procedure.</p>	A 955		



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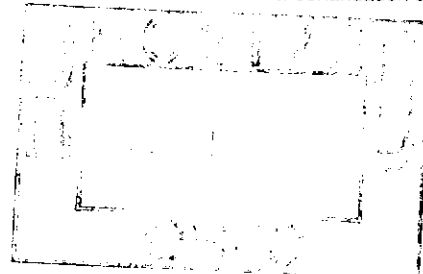
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A 955	<p>Continued From page 7</p> <p>All questions answered and consent given." There was no evidence of a consent signed by patient #7.</p> <p>A review of patient #8's medical record revealed the patient underwent a cholecystectomy on 4/23/08. On the 4/22/08 "Exam/Report", the surgeon documented: "Goals, risks, complications and alternatives of open cholecystectomy vs. attempted laparoscopic cholecystectomy discussed. Under the "Patient Education" section, the surgeon noted the following: "Appears ready to understand and learn from our discussion. No apparent learning barriers were identified from our verbal interactions. Explained diagnosis and treatment plan; patient appears to understand the content of our discussion." There was no evidence of a consent form signed by patient #8.</p> <p>A review of patient #9's medical record revealed the patient was seen in the Emergency Room and was then referred to neurology where patient #9 received a lumbar puncture (LP). The Emergency Room physician documented: "I consented him for LP after explaining risks and benefits ." There was no evidence of a consent form signed by patient #9.</p> <p>Hospital surgical and administrative staff were interviewed on 5/22/08 between from 8:30 - 9:15 AM and 4:30 - 6:00 PM during the medical record reviews for patients 1 - 9. Those present were the Acting Administrator (D), Quality Manager (E) and nursing supervisor ( F) and nursing manager (G) from the surgery units. The surgical nurse manager (staff G), the Chair of Surgery, (H) and the quality manager (E) verified there were no surgical consent forms signed by the patient or</p>	A 955			



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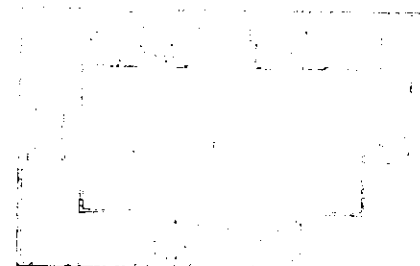
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A 955	<p>Continued From page 8 their representative.</p> <p>A review of 3 transplant recipient medical records open record, (L-1, Liver Program) and closed record (P-1, Pancreas Program) and closed record (PK-1) Pediatric Kidney Program revealed there was no evidence of a patient signed consent form for surgery.</p> <p>A review of P-1's medical record reviewed on 5/21/08 revealed P-1 underwent a pancreas transplant on July 21, 2007. The surgeon documented in the 7/21/07 "Hospital Notes": "discussed- risks/benefits/alternatives complications from transpt surg advanced directives team approach. Pt (patient) agrees to ok" P-1 when interviewed on 5/20/08 at 8:20 PM remembered talking about the risks and dangers of transplants but did not remember signing a consent form. There was no evidence of a consent form signed by patient P-1 for the transplant surgery in P-1's medical record. This was confirmed by interview on 5/21/08 at 7:22 AM, with the organ Pre-transplant Coordinator (I) and transplant surgeon (K) present during the review of P-1's medical record.</p> <p>There was no evidence of a patient signed surgical consent form for liver transplant recipient L-1. A review of the "Lists of Liver Transplants performed after 6/28/07" and patient # L-1's medical record revealed the patient underwent a liver transplant on May 17, 2008. On 5/17/08 the physician documented on the "Liver Transplant Hospital Service Miscellaneous" record under "Consent": "Risks benefits, outcomes, potential complications, alternatives to liver transplantation were explained to the patient in detail to include, but not limited to bleeding, infection, vascular</p>	A 955			



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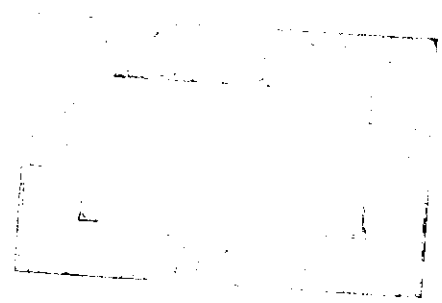
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A 955	<p>Continued From page 9</p> <p>thrombosis and death. Patient verbalized understanding and wished to proceed." There was no evidence of a consent form signed by the patient for the transplant procedure.</p> <p>There was no evidence of a parent/guardian signed consents for pediatric kidney recipient PK-1. A review of PK-1's medical record reviewed on 5/22/08 revealed the 17-year-old patient underwent a kidney transplant on May 2, 2008. On the "Hospital Admission Note" dated May 2, 2008 9:27 the physician documented under "PLAN": "OK-A for general anesthesia and deceased-donor kidney transplant. Discussed possible delayed graft function, and the need for posttransplant dialysis. The patient and his family are understanding." In a "Progress Note" dated 5/22/08 the surgeon documented under "Informed Consent": "Discussed risks, goals, alternatives, advance directives, and necessity of other members of the team participating in the procedure with patient and parent. The patient and parent had a chance to have any questions about this procedure answered, understand(s) and wish(es) to proceed. The patient consented to the possibility of blood transfusion. Patient agrees to proceed to the operating room today May 2, 2008 for a deceased donor kidney transplant." There was no evidence of a patient/parent signed consent form for surgery in the medical record.</p> <p>The Rochester Methodist Hospital transplant programs' policy "Recipient Informed Consent", 11/20/2007, was reviewed by the surveyors on 5/22/08. The policy indicated that "Informed consent will be documented in the electronic medical record and the patient will verbally indicate understanding." The policy did not</p>	A 955			



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A 955	<p>Continued From page 10 require a consent form signed by the patient.</p> <p>A Liver Pre-Transplant Coordinator (A) was interviewed on 5/22/2008 at 10:15 AM. She stated that a consent for evaluation for surgery was signed when the patient was seen in the Transplant clinic. She stated that documentation of the risks, complications and alternatives are documented by the surgeon and would be found in the progress notes in the medical record.</p> <p>The Nursing Administrator for the transplant programs (C) was interviewed on 5/20/08 at 12:10 PM about written surgical consents. The nurse administrator indicated that "There is no written surgical consent." "We don't use them here." She indicated that the surgeon documents that informed consent was given in the medical record.</p> <p>The Mayo Clinic policy and procedure governing hospital and transplant center patients " Informed Consent and Medical Decision Making " last approved by the Clinical Practice Committee on 6/28/05 states under Procedure Statement 2: " Physician judgment dictates the content of the consent discussion in any particular case, but generally major or common risks, benefits, alternatives and roles and responsibilities of the care team members (such as residents, fellows, physician assistants, surgical technicians, or other allied health practitioners) performing significant interventional tasks should be discussed. The patient may be advised that a care team member's name and role is documented in the medical record. The discussion, except in case of emergency, will occur prior to the procedure/intervention for which consent is obtained." Procedure Statement 4</p>	A 955		



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

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>240061</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>C</b> <b>05/22/2008</b>
NAME OF PROVIDER OR SUPPLIER  <b>ROCHESTER METHODIST HOSPITAL</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>201 WEST CENTER STREET ROCHESTER, MN 55902</b>		
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A 955	Continued From page 11 stated: "A reference to discussions with the patient and patient consent may be indicated in one of several places in the medical record including General History Notes, Clinical Notes, or the Emergency Department record. Informed consent may also be indicated on specific records such as those noted below: *Sedation - Sedation and Procedure Record or Anesthesia Record *Blood - Transfusion Order Form *Procedures - Sedation and Procedure Record"  An interview with hospital administrative and surgical staff occurred on 5/22/08 from 4:30 - 6:00 PM . Present were the Chief of the Department of Surgery (H), legal counsel (B) the Quality Management Services staff and administrator. The staff from Quality Management Services (E) stated that "typically" Mayo Clinic does not obtain signed informed consent forms for surgical procedures. This was also confirmed by the Chief of the Department of Surgery. The facility's legal representative ( B) indicated that Mayo did use an informed consent form signed by the patient/representative for research , electric shock therapy, some blood transfusions, sterilizations and when state law mandated such a consent. When asked about when the Federal law mandates the consent the legal representative (B) did not respond. Later she indicated they didn't agree with federal definition of "written consent". When questioned about policies that set forth minimum standards of information to be covered in the informed consent process the Chief of Department of Surgery (H) indicated the extent of the discussion is left up to the individual surgeon and it would depend on the nature and risk of the procedure.	A 955			

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