

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

PRINTED: 09/21/2012
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 360048	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED C 08/21/2012
NAME OF PROVIDER OR SUPPLIER UNIVERSITY OF TOLEDO MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 3000 ARLINGTON AVENUE TOLEDO, OH 43699		
(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 Substantial Allegation Survey OH00066791 An entrance conference was held with the Vice Provost and Associate Vice President on 08/16/12 at 9:00 A.M. An exit conference was held on 08/21/12, at 4:00 P.M. with the Vice Provost, President, Associate Vice President, and other administrative staff. The following deficiencies are based on the substantial allegation survey completed on 08/21/12.	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: Based on interview, clinical record review, policy review and observation, the facility failed to ensure adequate supervision and communication was provided in the operating room and failed to have adequate policies in place to achieve a high standard of patient care to prevent the disposal of a viable donor kidney for one of three sampled living donor patients (Patient #9) reviewed, failed to follow the facility's policy regarding the documentation of the time an organ arrives in the operating room for transplant for two of three sampled patients (Patients #11 and #13) and failed to maintain humidity levels in two operating rooms (rooms 8 and 9) per facility policy.	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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A 940	<p>Continued From page 1</p> <p>On 08/16/12, at 9:00AM during the entrance conference, the Vice Provost confirmed all kidney transplant surgeries, involving both living and deceased donors, have been stopped and the hospital has notified UNOS.</p> <p>Findings:</p> <p>The clinical record review for Patient #9 was completed on 08/21/12. The clinical record review revealed Patient #9 was admitted to the facility on 08/10/12 with a diagnosis of kidney donation. A pre-operative progress note dated 08/10/12 stated the planned procedure was a right laproscopic donor nephrectomy. A review of the operative report for the procedure, dictated on 08/20/12, revealed after the kidney was removed, it was wrapped in a lap sponge and placed in a slush machine and covered with additional cold slush. The report stated the circulating nurse and scrub nurse (the 'scrub tech' according to the case staff list) were informed the kidney was in the slush machine. The report stated, "As the skin was being closed it became apparent that the kidney was no longer in the slush machine" and "investigation of this fact revealed that the circulating nurse had inadvertently discarded the kidney."</p> <p>Please refer to 482.51(a)(1); Tag A942, Operating Room Supervision, for further details.</p> <p>On 08/21/12 at 10:19 A.M. Staff A, administrative staff, confirmed the clinical record reviews for Patients #11 and #13 did not indicate when the organ entered the operating room prior to transplant.</p> <p>The hospital policy CC-04 for "Operating Room Air Temperature and Humidity Settings, Standard Operating Procedure" was presented for review.</p>	A 940			

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A 940	Continued From page 2 Item # 4 of the procedure reads, "humidity control will be within a range of 35% to 60% in all surgical areas. Alarm points will be tagged under 35% or over 60 % for corrective action with a preventative maintenance work order by building automation controls." At the time of the interview, Staff D and E could not explain why this procedure was not followed when the readings in rooms 8 and 9 were below 35% consistently since January, 2012, nor why the temperature and humidity are not monitored in the 4-suite ambulatory surgical area.	A 940			
A 942	Please refer to 482.51(b); Tag A951, Operating Room Policies, for further detail. 482.51(a)(1) OPERATING ROOM SUPERVISION The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy. This STANDARD is not met as evidenced by: Based on interview, clinical record review, policy review and observation, the facility failed to provide adequate supervision and communication resulting in a donor's kidney being carried out of the operating room, down a hall, into a dirty utility room, and flushed down a hopper. This affected one of three kidney donor patients reviewed, Patient #9, in a sample of 14 patients. Findings: The clinical record review for Patient #9 was completed on 08/21/12. The clinical record review revealed the patient was admitted to the facility on 08/10/12 with a diagnosis of kidney donation. Review of the patient's history and	A 942			

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A 942	<p>Continued From page 3</p> <p>physical dated 08/10/12 documented Patient #9 did not have any significant past medical history and was presenting for a kidney donation.</p> <p>A pre-operative progress note dated 08/10/12 documented the planned procedure was a right laproscopic donor nephrectomy. A post-operative progress note dated 08/10/12 stated the right kidney was removed.</p> <p>A review of the operative report for the procedure was completed on 08/21/12. The review revealed that after the kidney was removed, it was wrapped in a lap sponge and placed in a slush machine and covered with additional cold slush. The report documented the circulating nurse, Nurse B and the scrub nurse, Staff B (the 'scrub tech' according to the case staff list) were informed the kidney was in the slush machine. The report also documented, "As the skin was being closed it became apparent that the kidney was no longer in the slush machine" and "investigation of this fact revealed that the circulating nurse had inadvertently discarded the kidney."</p> <p>Review of the clinical record did not reveal documentation that identified where the kidney was in the operating room. The extent of the documentation in regard to the location of the kidney was one phrase: "kidney out at 12:09." On 08/21/12 at 8:15 A.M. Staff A, administrative staff, confirmed the location of the removed kidney from the living donor was not documented in the clinical record.</p> <p>Circulating Nurse A, who inadvertently disposed of the kidney, was interviewed on 08/16/12 at</p>	A 942			

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A 942	<p>Continued From page 4</p> <p>12:45 PM. Nurse A stated that soon after the kidney was removed she was relieved for break by the relief circulating Nurse B. According to the facility's investigation Nurse A left for lunch at 12:15 PM, after giving report to Nurse B and returned to the operating room after lunch at approximately 1:05 PM. Nurse A stated that because she was on break she wasn't in the operating room when the surgeon announced the kidney was being placed in the slush machine. Nurse A stated she took the contents of the slush machine, without realizing the kidney was within the slush, left the operating room, and disposed of the contents in the hopper. Nurse A stated she thought the kidney was in the recipient's room because that is what usually happens.</p> <p>Relief circulating Nurse B, who was in the room when Physician B announced the kidney was in the slush machine, was interviewed on 08/16/12 at 2:24 PM. Nurse B stated that when Nurse A returned from her break Nurse A never asked to be briefed on what had occurred in the operating room during her absence. Nurse B also stated that she never saw Nurse A leave the room with the contents of the slush machine, and as best as she can remember, she was doing electronic charting when Nurse A left the room with the slush/kidney combination.</p> <p>On 08/16/12 scrub technician Staff B, was interviewed at 3:50 P.M. Staff B said she was in the operating room at approximately 1:05 P.M. and that she was responsible for the slush machine, but did not notice Nurse A take its contents, which included the kidney, out of the room.</p>	A 942			

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A 942	<p>Continued From page 5</p> <p>On 08/16/12 at 3:00 P.M. during an interview with Physician A, anesthesia resident, and at 3:15 PM, with Physician B, transplant surgeon, both stated that they did not notice Nurse A's activity around the slush machine, or her leaving the operating room with its contents.</p> <p>On 08/21/12 at 12:30 P.M. during an interview, Staff C, administrative staff, said they have not yet figured out how circulating Nurse A could take the slush with the kidney in a 13-gallon size bag out of the room without Nurse B, Physician A and B, and Staff B not noticing anything out of the ordinary.</p> <p>On the morning of 08/16/12 a tour was completed with Staff F, a representative from surgical services, of an operating room set up like the one used for Patient #9 . The tour revealed Nurse A had to have walked one-half the square room's perimeter and past Nurse B and Staff B to take the contents of the slush machine from one corner of the room to the only exit door, and then down the hall to the soiled utility room that contained the hopper.</p> <p>A review of the documentation of the facility's investigation revealed the usual process for emptying the slush machine was not followed as this is usually done by the perioperative techs or the surgical scrub tech instead of the circulating nurse. On 08/21/12 at 11:50 A.M. during an interview, Staff A, administrative staff, stated there wasn't a policy that explicitly stated who was responsible for the slush machine, its contents, and the removal of the contents.</p> <p>On 08/20/12 at 1:15 PM, in an interview, Staff H,</p>	A 942			

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A 942	<p>Continued From page 6</p> <p>a scrub technician, stated there are exceptions to when items can come out of the operating room prior to the patient leaving. Examples given by Staff H included when the case was 'simple', but staff H could not say who decides or what makes a case simple.</p> <p>Further review of the facility's investigation revealed the process of not removing anything from the room until the drapes are removed from the patient was not followed. According to the operative report Patient #9 was still on the operating table and the physicians were closing Patient #9's skin.</p> <p>On 08/21/12 six days after the event, the facility was asked for the prior policy/policies pertaining to the communication between the participants of the operating room staff and the relief staff and the policy for the responsibilities of the staff pertaining to the slush machine and disposal of waste. The policy presented for review on 08/20/12 was titled "intra Operative hand Off Communication" and had an effective date of 08/16/12. The policy stated a nurse being relieved will be responsible for initiating a process whereby information will be shared with the one providing the relief. The policy stated the sharing of information must be completed before the nurse who is being relieved leaves the room and must occur as soon as the relief nurse enters the operating room. The items of information to be shared includes procedural status and implants used/available in the room. When the policy was presented it was introduced as the facility's policy from the effective date forward.</p> <p>Another policy titled "Break Down" also with an</p>	A 942			

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A 942	Continued From page 7 effective date of 08/16/12 was presented. This policy stated "Operating Room contents will remain in the operating room until the patient physically leaves the operating room following a surgical procedure. It is the responsibility of the operating room circulating nurse to ensure compliance with this policy." No other policy/policies was presented representative of the facility's procedures prior to the incident that occurred on 08/10/12.	A 942			
A 951	This deficiency substantiates complaint number OH00066791. 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. This STANDARD is not met as evidenced by: Based on interview, policy review, and clinical record review, the facility failed to have policies in place to prevent a donor kidney from being taken out of the operating room and flushed down a hopper, rendering the kidney unusable. This affected one of three sampled living donor patients, Patient #9. In two other procedures the facility failed to follow its own policy to document the time a transplant organ arrives in the operating room. This affected two of three sampled kidney recipient patients, Patient #11 and #13. Further, the facility failed to follow their policy regarding the maintenance of humidity levels in the operating rooms. This has the potential to affect all patients receiving surgical	A 951			

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A 951	<p>Continued From page 8 services.</p> <p>Findings:</p> <p>1. The clinical record review for Patient #9 was completed on 08/21/12. The clinical record review revealed the patient was admitted to the facility on 08/10/12 with a diagnosis of kidney donation. Review of the patient's history and physical dated 08/10/12 documented Patient #9 did not have any significant past medical history and was presenting for kidney donation.</p> <p>A review of the operative report for the procedure was completed on 08/21/12. The review revealed that after the kidney was removed, it was wrapped in a lap sponge and placed in a slush machine and covered with additional cold slush. The report documented the circulating nurse, Nurse B and the scrub nurse, Staff B (the 'scrub tech' according to the case staff list) were informed the kidney was in the slush machine. The report also documented, "As the skin was being closed it became apparent that the kidney was no longer in the slush machine" and "investigation of this fact revealed that the circulating nurse had inadvertently discarded the kidney."</p> <p>Review of the clinical record did not reveal documentation that identified where the kidney was in the operating room. The extent of the documentation in regard to the location of the kidney was one phrase: "kidney out at 12:09." On 08/21/12 at 8:15 A.M. Staff A, administrative staff, confirmed the location of the removed kidney from the living donor was not documented in the clinical record. Also on 08/21/12 at 1:36 P.M.</p>	A 951			

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A 951	<p>Continued From page 9</p> <p>Staff A stated they did not have a policy in place requiring an operating room clinician to document the location of a donor kidney from removal up to leaving the operating room.</p> <p>On 08/21/12, the facility was asked for the policy/policies pertaining to the communication between the participants of the operating room staff and the relief staff and the policy for the responsibilities of the staff pertaining to the slush machine and disposal of waste. The policy presented for review on 08/20/12 was titled "intra Operative hand Off Communication" and had an effective date of 08/16/12. The policy stated a nurse being relieved will be responsible for initiating a process whereby information will be shared with the one providing the relief. The policy stated the sharing of information must be completed before the nurse who is being relieved leaves the room and must occur as soon as the relief nurse enters the operating room. The items of information to be shared includes procedural status and implants used/available in the room. When the policy was presented it was introduced as the facility's policy from the effective date forward.</p> <p>Another policy titled "Break Down" also with an effective date of 08/16/12 was presented. This policy stated "Operating Room contents will remain in the operating room until the patient physically leaves the operating room following a surgical procedure. It is the responsibility of the operating room circulating nurse to ensure compliance with this policy."</p> <p>No other policy/policies was presented representative of the facility's procedures prior to</p>	A 951			

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A 951	<p>Continued From page 10 the incident that occurred on 08/10/12.</p> <p>Please refer to 482.51(a)(1); Tag A942, Operating Room Supervision, for further details.</p> <p>2. Review of the policy "Organ Transplantation" effective 01/17/12 stated OR staff should document the time the organ is received into the operating suite. On 08/21/12 at 10:19 A.M. Staff A, confirmed the clinical record did not indicate when the organ entered the operating room prior to transplant.</p> <p>The clinical record review for Patient #11, a kidney donor, was completed on 08/21/12. The clinical record review revealed the organ was procured on 05/24/12. The extent of the charting in regard to the location of the kidney from removal from the patient to leaving the room was a nursing note dated 05/24/12 at 12:02 P.M. that documented the artery clamp time, and at 05/24/12 at 12:07 P.M. documented the time of the perfusion of the kidney on the cleaning tray. On 08/21/12 at 9:45 A.M. in an interview Staff C, administrative staff, confirmed there wasn't any further documentation of the kidney's location.</p> <p>The clinical record review for Patient #13 was completed on 08/21/12. The clinical record review revealed the patient who had a diagnosis of end-stage renal disease received a kidney transplant on 07/19/12. The clinical record review did not reveal when the organ entered the operating room prior to transplant.</p> <p>3. A tour of the main surgical area was conducted on 08/17/12 at 9:40 A.M.. During the tour at 10:10 A.M., Staff F and G stated that the</p>	A 951			

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A 951	<p>Continued From page 11</p> <p>operating room suites do not contain temperature and humidity readings and/or control. If a member of the surgical team requests a temperature adjustment, a call is made to the air handler control desk and the adjustment is made.</p> <p>Interviews were conducted with Staff D and E on 08/17/12 at 1:55 P.M.. Staff D stated that the hospital air handling system is automated. Set points for the temperature and humidity are established and the air handler is equipped to maintain each room within the preset parameters automatically. According to hospital policy, the humidity levels are to remain between 35% and 60%. Each morning at approximately 7:00 A.M. a reading is taken of the temperature and humidity of each of the 11-suite main operating rooms. These readings are printed and kept in a log book. The log book was provided for review. Review of the log book revealed that since January 1, 2012 the humidity level in operating room 8 was reading 25.4 %, and the humidity level in operating room 9 was reading 26.1%. The log book did not indicate that corrective action was taken for either room 8 or 9, nor were surgical cases canceled based on the low readings. Staff C reported that between January, 2012 and July, 2012, 482 cases had been performed in room 8 and 139 cases performed in room 9.</p> <p>Staff D and E revealed on 08/17/12 at 2:00 P.M. during interview, that the temperature and humidity levels of the 4-suite ambulatory surgical area were not monitored. Those components are checked annually during the preventative</p>	A 951			

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FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 360048	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED C 08/21/2012
NAME OF PROVIDER OR SUPPLIER UNIVERSITY OF TOLEDO MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 3000 ARLINGTON AVENUE TOLEDO, OH 43699		
(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 12 maintenance. The last recorded preventative maintenance of the air handler for the 4-suite ambulatory surgical area was completed on 2/22/12. Interview with Staff D and E was conducted again on 08/20/12 at 4:00 P.M.. The hospital policy for "Operating Room Air Temperature and Humidity Settings, Standard Operating Procedure" was presented for review. Item # 4 of the procedure reads, "humidity control will be within a range of 35% to 60% in all surgical areas. Alarm points will be tagged under 35% or over 60 % for corrective action with a preventative maintenance work order by building automation controls." At the time of the interview, Staff D and E could not explain why this procedure was not followed when the readings in rooms 8 and 9 were below 35% consistently since January, 2012, nor why the temperature and humidity are not monitored in the 4-suite ambulatory surgical area.	A 951			