STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	449806	A. BUILDING _____ B. WING _____	C 07/17/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
METHODIST HC TRANSPLANT	1265 UNION AVENUE MEMPHIS, TN 38104

(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
X 041	482.82 DATA SUBMIT/EXPERIENCE/OUTCOMES - REAPPROVAL Except as specified in paragraph (d) of this section and §488.61 of this chapter, transplant centers must meet all data submission, clinical experience, and outcome requirements in order to be re-approved. This CONDITION is not met as evidenced by: Based on review by the Centers for Medicare & Medicaid Services (CMS) of the January 2014 outcomes calculated by the Scientific Registry of Transplant Recipients (SRTR), the Adult Liver (ALI) transplant program failed to ensure that the CMS outcome requirements were met for the 1-year patient survival rates and the 1-year graft survival rates. Findings: 1. The Adult Liver (ALI) program ' s most recent outcomes data from the January 2014 Scientific Registry of Transplant Recipients (SRTR) Center Specific Report indicates that for patients receiving liver transplants between 07/01/2010 - 12/31/2012, the observed patient death and graft failure rates were higher than expected and considered unacceptable as outlined in X045. See X045 for specific SRTR reported data results for patient death and graft failure rates.	X 041	A comprehensive review of the ALI program was conducted, and contributing factors to decreased outcomes were identified and analyzed by a multidisciplinary team. Related indicators were incorporated into the ALI QAPI plan (for example, any patient listed having any relative contraindications must be discussed in the QAPI meeting). The ALI program also validated patient data in Unet to ensure accurate expected patient and graft survival rates in SRTR reporting. An outside consultant validated expected patient mortality and graft survival rates and enabled the ALI program to utilize software that produces predictive data which will be used to proactively identify and improve mortality outcomes for future cohorts. Transplant staff was educated on objectively and consistently evaluating the Functional Status of patients in each phase of the transplant process. Multidisciplinary Grand Rounds were performed by Program Director to educate and promote stringent adherence to selection criteria and higher scrutiny of patients with potential relative contraindications; related and appropriate indicators were incorporated into the ALI QAPI plan. The ALI program has successfully recruited and hired a dedicated Director of Transplant Quality. This associate will be in charge of data analysis, leading investigations on deaths and graft failures per the QAPI plan guidelines,working with the multidisciplinary team to implement	5/31/14 7/21/14
X 045	482.82(c)(3) OUTCOME: PATIENT/GRAFT SURVIVAL - REAPPROVAL CMS will not consider a center's patient and graft survival rates to be acceptable if: (i) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient	X 045	change, and monitoring improvement related to all QAPI activity. A written comprehensive data-driven plan for the QAPI program was developed by the Transplant Institute Administrator and approved by the Transplant Institute Executive Committee to address the individual components of the	

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

ADMINISTRATOR 7/25/14

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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X 045	Continued From page 1 survival rate and graft survival rate; and (ii) All three of the following thresholds are crossed over: (A) The one-sided p-value is less than 0.05, (B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and (C) The number of observed events divided by the number of expected events is greater than 1.5. This ELEMENT is not met as evidenced by: Based on review of data from the January 2014 Scientific Registry of Transplant Recipients (SRTR) Center Specific Report, the ALI program did not meet the regulatory outcome requirements outlined in CFR 482.82(c)(3) for 1-year patient and graft survival rates. Findings: 1. Review of the SRTR risk-adjusted outcomes report dated January 2014 revealed that the actual 1-year patient survival rate was significantly lower than expected for ALI patients transplanted between 07/01/2010 and 12/31/2012. The expected number of patient deaths (based on patient and donor characteristics) was 17.88; the actual number of patient deaths was 28. This is a statistically significant difference (i.e., p-value is 0.016). 2. Review of the SRTR risk-adjusted outcomes report dated January 2014 revealed that the actual 1-year graft survival rate was significantly lower than expected for ALI patients transplanted between 07/01/2010 and 12/31/2012. The expected number of graft failures (based on patient and donor characteristics) was 27.93; the actual number of graft failures was 43. This is a statistically significant difference (i.e., p-value is	X 045	transplant phases for the ALI program. A transplant-specific adverse event policy was incorporated with the QAPI program which addresses the process for identification and analysis of adverse events for all programs and phases of transplant. The written description of the QAPI program includes the following elements: a) individual members identified by name, title and roles and responsibilities; b) methods of operating and decision making; c) objective measures by which the quality data is collected and analyzed; d) frequency for review of program performance and reporting to the QAPI Committee and hospital-wide quality program; e) method by which key findings and recommendations are reported to key stakeholders; f) designation of individuals responsible for monitoring the QAPI program of the Transplant Institute; g) evidence of tracking and implementing recommendations for improvement; h) evidence of ongoing compliance with changes implemented by the QAPI committee; and i) evidence of broad representation of issues relevant to the members of the multidisciplinary team. A documented mechanism for communicating data driven PI information reflecting the entire cycle of quality assessment from identification of opportunity to sustained improvement was developed for the ALI program. The Transplant Institute's QAPI program developed objective measures and uses them to evaluate activities and outcomes related to transplantation and donation.The QAPI committee developed process and outcome measures for Pre, Peri and Post phases of transplant for the ALI program.	5/31/14

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X 045	Continued From page 2 0.005).	X 045	The QAPI dashboard includes data measures to indicate improvement for Performance Improvement measures. The Transplant Institute developed specific metrics to ensure that performance improvement is tracked and sustained for all phases of the ALI program. A QAPI mechanism was developed to ensure that problems are promptly identified and if needed long term measures are established. These measures are further monitored and evaluated on a continuous basis to ensure compliance through a Transplant QAPI dashboard. The QAPI process also ensures that actions and tracking of performance measures relate to the objective measures that evaluate the programs' performance with regard to transplantation and outcome activities for all phases of the AKO, ALI, APA and Living Donor Programs. Staff are informed of the metrics and outcomes of all measures on the QAPI dashboard on a monthly basis. The ALI program experienced two patient deaths from January-June of 2014 out of 54 transplants, (of which were the two graft failures). A Root Cause Analysis will be completed for these deaths and reported to the QAPI committee. In the data from the July 2014 Scientific Registry of Transplant Recipients (SRTR) Center Specific Report, the ALI program met the regulatory outcome requirements outlined in CFR 482.82(c)(3) for 1-year patient and graft survival rates.	8/22/14 7/1/14

Mortality and graft survival is monitored monthly at QAPI meetings and an investigation per the QAPI plan guidelines is conducted on each occurrence. The findings are presented at the Transplant Institute Executive Council and it is this bodies' responsibility to ensure 100% adherence to this POC related to this Condition and Element at inception and then on an annual basis.

Name and Title of Individual Responsible: Oliver Banks, *Transplant Administrator*