STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
	399807	A. BLDG: __00_____ B. WING: _____	05/06/2022

NAME OF PROVIDER OR SUPPLIER:	STREET ADDRESS, CITY, STATE, ZIP CODE:
MILTON S HERSHEY MEDICAL CENTER - TRANSPLANT CENTER STATE LICENSE NUMBER: **P6IG0101**	**500 UNIVERSITY DRIVE, P. O. BOX 850 HERSHEY, PA 17033**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED 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	(X5) COMPLETE DATE
X 0000	INITIAL COMMENT	X 0000		

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

Any deficiency statement ending with an asterisk (*) denotes a deficiency which may be excused from correction providing it is determined that other safeguards provide sufficient protection to the patients. The findings stated above are disclosable whether or not a plan of correction is provided. The findings are disclosable within 14 days after such information is made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

This form is a printed electronic version of the CMS 2567L. It contains all the information found on the standard document in much the same form. This electronic form once printed and signed by the facility administrator and appropriately posted will satisfy the CMS requirement to post survey information found on the CMS 2567L.

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X 0000	Continued from page 1 A Medicare Transplant Complaint survey was conducted on site from 05/04/22 through 05/06/22. The entrance conference convened on 05/04/22 at 9:30 AM with the Hospital's President (P1), Sr. Vice President and Chief Operating Officer (COO), Quality Manager of Solid Organ Transplant (QM), Director of Solid Organ Transplant (TD), and the Chief Quality Officer (CQO). An exit conference conducted on 05/06/22 at 8:15 PM included the Hospital President (P1), Sr. Vice President and Chief Operating Officer (COO), Quality Manager of Solid Organ Transplant (QMSOT), Director of Solid Organ Transplant (TD), Chief Quality Officer (CQO), Chief Medical Officer (CMO), Adult Kidney Only (AKO)/Adult Liver Only (ALI) Transplant Surgeon (TS2), Director of Regulatory (DR), and the Manager of Regulatory (MR). All citations are from samples drawn from cases after the effective date of the Subpart E requirements within the last three years. Each	X 0000		

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X 0000	Continued from page 2 deficiency statement includes a reference to the organ program to which the deficient practice applies. The Medicare Transplant Complaint survey included the following type of organ transplant programs: Adult Kidney Only (AKO), and Adult Liver Only (ALI). Complaint: PA00057383 was substantiated based on the facts obtained during the survey. The following Condition level deficiencies were cited for the AKO, and the ALI transplant programs as a result of 42 CFR §482.72 through §482.104. X011 §482.74 and X149 §482.102 In addition, the following Standard level deficiencies related to the CMS Federal Regulations for Transplant Centers at 42 CFR §482.72 through §482.104 were cited for the AKO, and the ALI transplant programs. X012 §482.74(a)(1), X103 §482.96(b)(2), X154§482.102(a)(4), and X156 §482.102(a)(6)	X 0000		

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X 0000	Continued from page 3 The following Condition level deficiency was cited for the CMS Federal Regulations for Hospitals set forth at 42 CFR Part 482. A-0940 §482.51 Additionally, the following Standard level deficiencies were cited for the CMS Federal Regulations for Hospitals set forth at 42 CFR Part 482. A-0341§482.22(b)(4), A-0446 §482.24(c)(4)(v), and A-0955 §482.51(b)(2).	X 0000		
X 0011 AKO ALI		X 0011		

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X 0011 AKO ALI	Continued from page 4 482.74 NOTIFICATION TO CMS 482.74 Condition of Participation: Notification to CMS. (a) A transplant program must notify CMS immediately of any significant changes related to the program's transplant program or changes that could affect its compliance with the conditions of participation. Instances in which CMS should receive information for follow-up, as appropriate, should include, but are not limited to; This REQUIREMENT is not met as evidenced by:	X 0011	Plan for correction: - The Solid Organ Transplant Quality Manager submitted the Adult Kidney Only program application to UNOS on 4/27/2022, which was within the required 30 days as the notification was sent on 4/5/2022. Additional information was requested on 4/28/2022 and provided on 5/9/2022. - On 5/6/2022 the Director of Solid Organ Transplant submitted a letter to CMS with notification of 1/3/2022 change in Chief of Division of Abdominal Transplant and provided a copy of this letter to the on-site CMS surveyor. - The Abdominal Transplant Division Chief, Director of Solid Organ Transplant and the Solid Organ Transplant Quality Manager updated and approved the policy that outlines the roles and responsibilities of informing OPTN and CMS of any key personnel changes (TXP-2PM CMS and OPTN/UNOS Compliance of	Completion Date: **06/15/2022** Status: **APPROVED** Date: **09/01/2022**

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X 0011 AKO ALI	Continued from page 5	X 0011	Regulatory Required Communications: Key Personnel and Program Status) for the Adult Kidney Only and Adult Liver transplant programs on 6/6/2022 (see attachment C). All administrative transplant team members are required to review and sign off on understanding. - Upon hire, as part of their orientation, the Director of Solid Organ Transplant will provide education to the Abdominal Transplant Program Manager regarding their roles and responsibilities for informing CMS and OPTN of key personnel changes in the Adult Kidney Only transplant program. - Key personnel changes that require notification to CMS and OPTN are now included as a standing agenda item for the twice monthly solid organ transplant leadership/quality meetings. Monitoring/tracking procedures:	

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X 0011 AKO ALI	Continued from page 6	X 0011	- Effective 6/15/2022, the Solid Organ Transplant Quality Manager will monitor all future key personnel changes utilizing a key personnel change checklist containing the following elements: 1. Prior key personnel and date of when hospital was notified of their planned departure, when CMS and OPTN notified of the planned departure date. 2. New key personnel and the dates of: a. CMS and OPTN notification b. hire c. privileging d. arrival e. assumption of the role f. application submission g. application approval by the MPSC - The Quality Associate will document compliance on the program's QAPI dashboard (see attachment A). The QAPI dashboard will be reviewed at each QAPI meeting. Any non-compliance will be addressed by the Director of Solid	

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X 0011 AKO ALI	Continued from page 7	X 0011	Organ Transplant. - At the time of recruitment for all new transplant physicians/surgeons, the Director of Solid Organ Transplant will maintain a checklist which will include: 1. training (residency/fellowship) 2. board certification 3. licensure 4. logs validating required patient care activities Individual Responsible for the Plan of Correction: The Director of Solid Organ Transplant Corrective actions completion date: 6/15/2022 with continued monitoring Plan for correction: - The Solid Organ Transplant Quality Manager submitted the Adult Liver program application to UNOS on 3/30/2022. Additional information was provided as requested by UNOS with the last request fulfilled on 4/12/2022.	

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X 0011 AKO ALI	Continued from page 8	X 0011	- On 5/6/2022 the Director of Solid Organ Transplant submitted a letter to CMS with notification of 1/3/2022 change in Chief of Division of Abdominal Transplant and provided a copy of this letter to the on-site CMS surveyor. - The Abdominal Transplant Division Chief, Director of Solid Organ Transplant and the Solid Organ Transplant Quality Manager updated and approved the policy that outlines the roles and responsibilities of informing OPTN and CMS of any key personnel changes (TXP-2PM CMS and OPTN/UNOS Compliance of Regulatory Required Communications: Key Personnel and Program Status) for the Adult Kidney Only and Adult Liver transplant programs on 6/6/2022 (see attachment C). All administrative transplant team members are required to review and sign off on understanding.	

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X 0011 AKO ALI	Continued from page 9	X 0011	- Upon hire as part of their orientation, the Director of Solid Organ Transplant will provide education to the Abdominal Transplant Program Manager regarding their roles and responsibilities for informing CMS and OPTN of key personnel changes in the Adult Liver transplant program. - Key personnel changes that require notification to CMS and OPTN are now included as a standing agenda item for the twice monthly solid organ transplant leadership/quality meetings. Monitoring/tracking procedures: - Effective 6/15/2022, the Solid organ Transplant Quality Manager will develop and monitor all future key personnel changes utilizing a key personnel change checklist containing the following elements: 1. Prior key personnel and date of when hospital was notified of their planned departure, when CMS and OPTN notified of the planned	

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X 0011 AKO ALI	Continued from page 10	X 0011	departure date. 2. New key personnel and the dates of: a. CMS and OPTN notification b. hire c. privileging d. arrival e. assumption of the role f. application submission g. application approval by the MPSC - The Quality Associate will document compliance on the program's QAPI dashboard (see attachment A). The QAPI dashboard will be reviewed at each QAPI meeting. Any non-compliance will be addressed by the Director of Solid Organ Transplant. - At the time of recruitment for all new transplant physicians/surgeons, the Director of Solid Organ Transplant will maintain a checklist which will include: 1. training (residency/fellowship) 2. board certification 3. licensure	

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X 0011 AKO ALI	Continued from page 11	X 0011	4. logs validating required patient care activities Individual Responsible for the Plan of Correction: The Director of Solid Organ Transplant Corrective actions completion date: 6/15/2022 with continued monitoring	

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X 0011 AKO ALI	Continued from page 12 Based on interview and document review, the Adult Kidney Only (AKO) program's staff failed to notify The Centers for Medicare and Medicaid Services, (CMS) of significant changes related to the center's transplant program or changes that could affect its compliance with the conditions of participation. Findings include: 1. In an interview on 05/04/22 at 11:30 AM, the President (P1) explained that the transplant program has had several changes in staff. In 2020 the Department Director and another surgeon retired, and another surgeon died (no specific dates provided). The new transplant surgeons (TS)3 and TS2's employment began at this facility on 01/03/22. TS2 started actively performing AKO transplant surgeries on 01/13/22. P1 explained that the paperwork to designate TS2 as the primary surgeon for the abdominal program was not submitted to the United Network for Organ Sharing (UNOS) until 03/25/22. Because of this oversite and what P1 described as other dereliction of	X 0011		

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X 0011 AKO ALI	Continued from page 13	X 0011		

duties, the transplant center's former Transplant Manager (FTM) was terminated on 04/11/22. Additionally, according to P1, TS4 was placed on administrative leave on 04/01/22. Under the hospital's legal advisement, no details were provided regarding TS4's administrative leave. These are significant changes that could affect the transplant program's ability to preform transplants. CMS was not informed of these changes.

2. An email correspondence from UNOS to the Quality Manager of Solid Organ Transplant (QMSOT) was reviewed on 05/05/22. The email dated 04/27/22 stated, "Here is the list of your staff in the key positions. You can update the Primary Program Administrator and Primary Data Coordinator roles in the Member Community portal through the Membership tab at the top. Primary program administrator and primary data coordinator will need to be updated under each applicable organ program at your hospital. You only need to make the change under the main program and not to the components (living donor or pediatric). If you need

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X 0011 AKO ALI	Continued from page 14 to do director updates let me know which organ and I will get you the document to make that change." As of 05/06/22, date of survey exit, the application for Primary Surgeon for the abdominal programs were not complete. 3. On 05/06/22, the Transplant Director (TD) provided the surveyor with copies of a letter drafted on 05/06/22 to CMS stating, "Please be advised effective January 3,2022, Penn State Milton S. Hershey Medical Center hired a new Chief for the Abdominal Transplant Program. [TS2] will replace [Retired Primary Transplant Surgeon [(RPTS)] in this leadership role. The AKO programs staff failed to make notification to CMS of the changes in their AKO program's key staff that could affect their ability to perform transplants, until after an onsite review by the surveyor. (See X012) Based on interview and document review, the Adult Liver (ALI) program's staff failed to notify The	X 0011		

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X 0011 AKO ALI	Continued from page 15 Centers for Medicare and Medicaid Services, (CMS) of significant changes related to the center's transplant program or changes that could affect its compliance with the conditions of participation. Findings include: 1. In an interview on 05/04/22 at 11:30 AM, the President (P1) explained that the transplant program has had several changes in staff. In 2020 the Department Director and another surgeon retired, and another surgeon died (no specific dates provided). The new transplant surgeons (TS)3 and TS2's employment began at this facility on 01/03/22. TS2 started actively performing ALI transplant surgeries on 01/13/22. P1 explained that the paperwork to designate TS2 as the primary surgeon for the abdominal program was not submitted to the United Network for Organ Sharing (UNOS) until 03/25/22. Because of this oversite and what P1 described as other dereliction of duties, the transplant center's former Transplant Manager (FTM) was terminated on 04/11/22.	X 0011		

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X 0011 AKO ALI	Continued from page 16 Additionally, according to P1, TS4 was placed on administrative leave on 04/01/22. Under the hospital's legal advisement, no details were provided regarding TS4's administrative leave. These are significant changes that could affect the transplant program's ability to perform transplants. CMS was not informed of these changes. 2. An email correspondence from UNOS to the Quality Manager of Solid Organ Transplant (QMSOT) was reviewed on 05/05/22. The email dated 04/27/22 stated, "Here is the list of your staff in the key positions. You can update the Primary Program Administrator and Primary Data Coordinator roles in the Member Community portal through the Membership tab at the top. Primary program administrator and primary data coordinator will need to be updated under each applicable organ program at your hospital. You only need to make the change under the main program and not to the components (living donor or pediatric). If you need to do director updates let me know which organ and I will get you the document to make that change."	X 0011		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
	399807	A. BLDG: __00_____ B. WING: _____	05/06/2022

NAME OF PROVIDER OR SUPPLIER:	STREET ADDRESS, CITY, STATE, ZIP CODE:
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X 0011 AKO ALI	Continued from page 17 As of 05/06/22, date of survey exit, the application for Primary Surgeon for the abdominal programs were not complete. 3. On 05/06/22, the Transplant Director (TD) provided the surveyor with copies of a letter drafted on 05/06/22 to CMS stating, "Please be advised effective January 3,2022, Penn State Milton S. Hershey Medical Center hired a new Chief for the Abdominal Transplant Program. [TS2] will replace [Retired Primary Transplant Surgeon [(RPTS)] in this leadership role." The ALI programs staff failed to make notification to CMS of the changes in their ALI program's key staff which could affect the ALI program's ability to perform transplants, until after an onsite review by the surveyor. (See X012)	X 0011		
X 0012 AKO ALI		X 0012		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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X 0012 AKO ALI	Continued from page 18 482.74(a)(1) CHANGE IN KEY STAFF MEMBERS 482.74(a)(1): Instances in which CMS should receive information for follow up, as appropriate, include, but are not limited to, change in key staff members of the transplant team, such as a change in the individual the transplant program designated to the OPTN as the program's "primary transplant surgeon" or "primary transplant physician." This REQUIREMENT is not met as evidenced by:	X 0012	Plan for correction: - The Solid Organ Transplant Quality Manager submitted the Adult Kidney Only program application to UNOS on 3/30/2022. Additional information was provided as requested by UNOS with the last request fulfilled on 4/12/2022. - On 5/6/2022 the Director of Solid Organ Transplant submitted a letter to CMS with notification of 1/3/2022 change in Chief of Division of Abdominal Transplant and provided a copy of this letter to the on-site CMS surveyor. - The Abdominal Transplant Division Chief, Director of Solid Organ Transplant and the Solid Organ Transplant Quality Manager updated and approved the policy that outlines the roles and responsibilities of informing OPTN and CMS of any key personnel changes (TXP-2PM CMS and OPTN/UNOS Compliance of Regulatory Required Communications: Key Personnel and	Completion Date: **06/15/2022** Status: **APPROVED** Date: **09/01/2022**

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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X 0012 AKO ALI	Continued from page 19	X 0012	Program Status) for the Adult Kidney Only and Adult Liver transplant programs on 6/6/2022 (see attachment C). All administrative transplant team members are required to review and sign off on understanding. - Upon hire as part of their orientation, the Director of Solid Organ Transplant will provide education to the Abdominal Transplant Program Manager regarding their roles and responsibilities for informing CMS and OPTN of key personnel changes in the Adult Kidney Only transplant program. - Key personnel changes that require notification to CMS and OPTN are now included as a standing agenda item for the twice monthly solid organ transplant leadership/quality meetings. Monitoring/tracking procedures: - Effective 6/15/2022, the Solid Organ Transplant Quality Manager	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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X 0012 AKO ALI	Continued from page 20	X 0012	will monitor all future key personnel changes utilizing a key personnel change checklist containing the following elements: 1. Prior key personnel and date of when hospital was notified of their planned departure, when CMS and OPTN notified of the planned departure date. 2. New key personnel and the dates of: a. CMS and OPTN notification b. hire c. privileging d. arrival e. assumption of the role f. application submission g. application approval by the MPSC - The Quality Associate will document compliance on the program's QAPI dashboard. (See attachment A). The QAPI dashboard will be reviewed at each QAPI meeting. Any non-compliance will be addressed by the Director of Solid Organ Transplant.	

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X 0012 AKO ALI	Continued from page 21	X 0012	- At the time of recruitment for all new transplant physicians/surgeons, the Director of Solid Organ Transplant will maintain a checklist which will include: 1. training (residency/fellowship) 2. board certification 3. licensure 4. logs validating required patient care activities Individual Responsible for the Plan of Correction: The Director of Solid Organ Transplant Corrective actions completion date: 6/15/2022 with continued monitoring b. Based on interview and document review, the Adult Liver (ALI) program's staff failed to notify The Centers for Medicare and Medicaid Services, (CMS) of changes in key staff member of the transplant team. Plan for correction: - The Solid Organ Transplant Quality Manager submitted the	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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X 0012 AKO ALI	Continued from page 22	X 0012	Adult Liver program application to UNOS on 3/30/2022. Additional information was provided as requested by UNOS with the last request fulfilled on 4/12/2022. - On 5/6/2022 the Director of Solid Organ Transplant submitted a letter to CMS with notification of 1/3/2022 change in Chief of Division of Abdominal Transplant and provided a copy of this letter to the on-site CMS surveyor. - The Abdominal Transplant Division Chief, Director of Solid Organ Transplant and the Solid Organ Transplant Quality Manager updated and approved the policy that outlines the roles and responsibilities of informing OPTN and CMS of any key personnel changes (TXP-2PM CMS and OPTN/UNOS Compliance of Regulatory Required Communications: Key Personnel and Program Status) for the Adult Kidney Only and Adult Liver transplant programs on 6/6/2022 (see	

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X 0012 AKO ALI	Continued from page 23	X 0012	attachment C). All administrative transplant team members are required to review and sign off on understanding. - Upon hire as part of their orientation, the Director of Solid Organ Transplant will provide education to the Abdominal Transplant Program Manager regarding their roles and responsibilities for informing CMS and OPTN of key personnel changes in the Adult Liver transplant program. - Key personnel changes that require notification to CMS and OPTN are now included as a standing agenda item for the twice monthly solid organ transplant leadership/quality meetings. Monitoring/tracking procedures: - Effective 6/15/2022, the Solid Organ Transplant Quality Manager will monitor all future key personnel changes utilizing a key personnel change checklist containing the	

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X 0012 AKO ALI	Continued from page 24	X 0012	following elements: 1. Prior key personnel and date of when hospital was notified of their planned departure, when CMS and OPTN notified of the planned departure date. 2. New key personnel and the dates of: a. CMS and OPTN notification b. hire c. privileging d. arrival e. assumption of the role f. application submission g. application approval by the MPSC - The Quality Associate will document compliance on the program's QAPI dashboard. (See attachment A). The QAPI dashboard will be reviewed at each QAPI meeting. Any non-compliance will be addressed by the Director of Solid Organ Transplant. - At the time of recruitment for all new transplant physicians/surgeons, the Director of Solid Organ	

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X 0012 AKO ALI	Continued from page 25	X 0012	Transplant will maintain a checklist which will include: 1. training (residency/fellowship) 2. board certification 3. licensure 4. logs validating required patient care activities Individual Responsible for the Plan of Correction: The Director of Solid Organ Transplant Corrective actions completion date: 6/15/2022 with continued monitoring	

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X 0012 AKO ALI	Continued from page 26 Based on interview and document review, the Adult Kidney Only (AKO) program's staff failed to notify The Centers for Medicare and Medicaid Services, (CMS) of changes in key staff member of the transplant team. Findings include: 1. In an interview on 05/04/22 at 11:30 AM, the President (P1) explained that the transplant program has had several changes in staff. In 2020 the Department Director and another surgeon retired, and another surgeon died (no specific dates provided). The new transplant surgeons (TS)3 and TS2's employment began at this facility on 01/03/22. TS2 started actively performing AKO transplant surgeries on 01/13/22. P1 explained that the paperwork to designate TS2 as the primary surgeon for the abdominal program was not submitted to the United Network for Organ Sharing (UNOS) until 03/25/22. Because of this oversite and what P1 described as other dereliction of duties, the transplant center's former Transplant	X 0012		

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X 0012 AKO ALI	Continued from page 27	X 0012		

Manager (FTM) was terminated on 04/11/22. Additionally, according to P1, TS4 was placed on administrative leave on 04/01/22. Under the hospital's legal advisement, no details were provided regarding TS4's administrative leave.

2. An email correspondence from UNOS to the Quality Manager of Solid Organ Transplant (QMSOT) was reviewed on 05/05/22. The email dated 04/27/22 stated, "Here is the list of your staff in the key positions. You can update the Primary Program Administrator and Primary Data Coordinator roles in the Member Community portal through the Membership tab at the top. Primary program administrator and primary data coordinator will need to be updated under each applicable organ program at your hospital. You only need to make the change under the main program and not to the components (living donor or pediatric). lf you need to do director updates let me know which organ and I will get you the document to make that change." As of 05/06/22, date of survey exit, the application for Primary Surgeon for the abdominal programs

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X 0012 AKO ALI	Continued from page 28 were not complete. 3. On 05/06/22, the Transplant Director (TD) provided the surveyor with copies of a letter drafted on 05/06/22 to CMS stating, "Please be advised effective January 3,2022, Penn State Milton S. Hershey Medical Center hired a new Chief for the Abdominal Transplant Program. [TS2] will replace [Retired Primary Transplant Surgeon [(RPTS)] in this leadership role. The AKO programs staff failed to make notification to CMS of the changes in their AKO program's key staff until after an onsite review by the surveyor. Based on interview and document review, the Adult Liver (ALI) program's staff failed to notify The Centers for Medicare and Medicaid Services, (CMS) of changes in key staff member of the transplant team. Findings include:	X 0012		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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X 0012 AKO ALI	Continued from page 29 1. In an interview on 05/04/22 at 11:30 AM, the President (P1) explained that the transplant program has had several changes in staff. In 2020 the Department Director and another surgeon retired, and another surgeon died (no specific dates provided). The new transplant surgeons (TS)3 and TS2's employment began at this facility on 01/03/22. TS2 started actively performing ALI transplant surgeries on 01/16/22. P1 explained that the paperwork to designate TS2 as the primary surgeon for the abdominal program was not submitted to the United Network for Organ Sharing (UNOS) until 03/25/22. Because of this oversite and what P1 described as other dereliction of duties, the transplant center's Transplant Manager (FTM) was terminated on 04/11/22. Additionally, according to P1, TS4 was placed on administrative leave on 04/01/22. Under the hospital's legal advisement, no details were provided regarding TS4's administrative leave. 2. An email correspondence from UNOS to the Quality Manager of Solid Organ Transplant	X 0012		

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X 0012 AKO ALI	Continued from page 30 (QMSOT) was reviewed on 05/05/22. The email dated 04/27/22 stated, "Here is the list of your staff in the key positions. You can update the Primary Program Administrator and Primary Data Coordinator roles in the Member Community portal through the Membership tab at the top. Primary program administrator and primary data coordinator will need to be updated under each applicable organ program at your hospital. You only need to make the change under the main program and not to the components (living donor or pediatric). lf you need to do director updates let me know which organ and I will get you the document to make that change." As of 05/06/22, date of survey exit, the application for Primary Surgeon for the abdominal programs were not complete. 3. On 05/06/22, the Transplant Director (TD) provided the surveyor with copies of a letter drafted on 05/06/22 to CMS stating, "Please be advised effective January 3,2022, Penn State Milton S. Hershey Medical Center hired a new Chief for the Abdominal Transplant Program. [TS2] will replace	X 0012		

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X 0012 AKO ALI	Continued from page 31 [Retired Primary Transplant Surgeon [(RPTS)] in this leadership role. The ALI programs staff failed to make notification to CMS of the changes in their ALI program's key staff until after an onsite review by the surveyor.	X 0012		
X 0103 AKO ALI		X 0103		

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X 0103 AKO ALI	Continued from page 32 482.96(b)(2) ANALYSIS/DOCUMENTATION OF ADVERSE EVENT 482.96(b)(2): The transplant program must conduct a thorough analysis of and document any adverse event… This REQUIREMENT is not met as evidenced by:	X 0103	Plan for correction: - Beginning 6/10/2022, the Quality Associate will begin to audit every Adult Kidney Only transplant patient and assess for unplanned returns to the Operating Room and unplanned readmissions within 30 days of transplant. Unplanned returns to the operating room have been added as a tracked item to the Transplant QAPI dashboard (see attachment A). The Quality Associate will ensure that a MIDAS report (patient safety event report) is submitted for each qualifying incident. Monitoring/tracking procedures: - Each qualifying incident will be reviewed at the Adult Kidney Only program's monthly Morbidity & Mortality conference. Any identified trends will be discussed by the abdominal transplant program's QAPI committee for recommendations or further review. - At the abdominal transplant program's QAPI committee,	Completion Date: **06/15/2022** Status: **APPROVED** Date: **09/01/2022**

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
	399807	A. BLDG: __00_____ B. WING: _____	05/06/2022

NAME OF PROVIDER OR SUPPLIER:	STREET ADDRESS, CITY, STATE, ZIP CODE:
MILTON S HERSHEY MEDICAL CENTER - TRANSPLANT CENTER	**500 UNIVERSITY DRIVE, P. O. BOX 850 HERSHEY, PA 17033**
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X 0103 AKO ALI	Continued from page 33	X 0103	identified trends in patient safety events will be analyzed. Based on the analysis recommendations for program improvement will be implemented. - Patient safety events requiring a higher level of peer review will be sent to the hospital's Professional Practice Evaluation Committee for a secondary review. Individual Responsible for the Plan of Correction: The Director of Solid Organ Transplant Corrective actions completion date: 6/15/2022 with continued monitoring b. Based on review of the transplant program's Quality Assessment Performance Improvement (QAPI) plan, medical record reviews, and interviews, the ALI programs staff failed to analyze an ALI post-op death with multiple returns to the OR prior to discharge in compliance with their QAPI plan to determine if any process improvements were needed. There	

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X 0103 AKO ALI	Continued from page 34	X 0103	were six transplant cases reviewed, KTR1 through KTR5 and LIRT1. LITR1 expired in the hospital prior to discharge. Plan for correction: - Beginning 6/10/2022, the Quality Associate will begin to audit every Adult Liver transplant patient and assess for unplanned returns to the Operating Room and unplanned readmissions within 30 days of transplant. Unplanned returns to the operating room have been added as a tracked item to the Transplant QAPI dashboard (see attachment A). The Quality Associate will ensure that a MIDAS report (patient safety event report) is submitted for each qualifying incident. Monitoring/tracking procedures: - Each qualifying incident will be reviewed at the Adult Liver program's monthly Morbidity & Mortality conference. Any identified trends will be discussed by the abdominal transplant program's QAPI committee for	

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X 0103 AKO ALI	Continued from page 35	X 0103	recommendations or further review. - At the abdominal transplant program's QAPI committee, identified trends in patient safety events will be analyzed. Based on the analysis recommendations for program improvement will be implemented. - Patient safety events requiring a higher level of peer review will be sent to the hospital's Professional Practice Evaluation Committee for a secondary review. Individual Responsible for the Plan of Correction: The Director of Solid Organ Transplant Corrective actions completion date: 6/15/2022 with continued monitoring	

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X 0103 AKO ALI	Continued from page 36 Based on review of the transplant program's Quality Assessment Performance Improvement (QAPI) plan and medical record reviews, and interviews, the AKO programs staff failed to recognize, report and analyze multiple patient returns to the Operating Room (OR) immediately post-op Adult Kidney Only (AKO) transplantation prior to discharge, and failed to recognize, report and analyze multiple transplant readmissions to the hospital post-discharge, to determine if trends were occurring that required a performance plan to effect change. There were six transplant cases, five kidney and one liver (see X103 ALI) that had to be returned to the OR post-transplant. The kidney cases included Kidney Transplant Recipient (KTR)1 through KTR5. None of these five kidney cases were reported for quality review. Findings include: 1. A review of the transplant program's Quality Assessment Performance Improvement (QAPI) plan determined AKO program has a	X 0103		

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X 0103 AKO ALI	Continued from page 37 comprehensive quality plan titled, "Kidney, Pediatric Kidney, Liver and Pancreas Transplant and Living Donor Specific QAPI Plan," effective date, 03/09/20 that defines and addresses the handling of Patient Safety Events, Incidents Serious Events and Sentinel Events. The plan states, 'Per hospital policy, A-09 HAM Patient Safety Event Reporting, a Patient Safety Event Report or Great Catch for Patient Safety card shall be completed immediately or within 24 hours of identification. Events reported via a Great Catch for Patient Safety card will be entered into the Electronic Patient Safety Event Reporting System (EPSEFS) (Midas) on the next business day. Should the EPSEFS be unavailable, the Great Catch for Patient Safety cards should be utilized ... Transplant specific adverse events may require reporting to regulatory bodies including OPTN/UNOS or CMS ... Per hospital policy, A-09 HAM Patient Safety Event Reporting, a Patient Safety Event Report or Great Catch for Patient Safety card shall be completed immediately	X 0103		

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X 0103 AKO ALI	Continued from page 38	X 0103		

or within 24 hours of identification. Events reported via a Great Catch for Patient Safety card will be entered into the Electronic Patient Safety Event Reporting System (EPSEFS) (Midas) on the next business day. Should the EPSEFS be unavailable, the Great Catch for Patient Safety cards should be utilized.

The abdominal transplant program will also use an Adverse Events collection form to identify Adverse Events that are not reported in the EPSEFS. These will include events that may not be considered adverse events by Kidney, Pediatric Kidney, Liver Pancreas Transplant and Living Donor Specific QAPI Plan the standards of the Hospital system but are something that the transplant program will capture. These will also include events that may have occurred outside of our medical system.

Reporting & Analysis
Once an event has been identified, it will be reported to the QAPI Analyst for transplant. The QAPI analyst will then determine if the event took

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X 0103 AKO ALI	Continued from page 39 place under the control of Penn State Health Milton S. Hershey Medical Center or its outpatient sites. If yes, then the event can be entered into Midas by either the QAPI Analyst or the clinical professional who reported the Adverse Event... If the event did not occur at Penn State Health Milton S. Hershey Medical Center, the event is not entered into the Midas system. The event will be investigated the same as above by the QAPI Analyst. The event will be added to the Adverse Event Log and analyzed as below. Any investigation will be done by the Abdominal Transplant Team. Once an event has been reported, it will be reviewed and assigned a harm score. The harm scores and their level of analysis are as follows. 1. Unsafe Conditions - Low 2. Event, No Harm - Low 3. Event, Harm - Moderate to High 4. Event, Death - High Components of a Thorough Analysis - Low	X 0103		

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X 0103 AKO ALI	Continued from page 40 Low level of analysis will be completed for adverse events with no resulted or expected patient harm. Low level analysis includes: Determining the relevance of adverse event for transplant patients. If relevant, an investigative report will be completed. These events will be reviewed for trends. Events can be escalated to a moderate analysis. These will include: "No Harm" events "Near Miss" events Infections will be reviewed for trends Rejection Episodes will be reviewed for trends Non-planned returns to the OR will be reviewed for trends. These may also be reviewed as a moderate or high review case. Death or graft failure greater than three years from transplant Moderate (Apparent Cause Analysis) - Moderate level of analysis will be completed for adverse events that resulted in temporary harm and/or required prolonged hospitalization. These events will be reviewed at the monthly program	X 0103		

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X 0103 AKO ALI	Continued from page 41 M&M meeting. Presentations will have basic information only. At any time, events can be escalated to a high analysis. These will include: A patient death while on the waitlist A patient death or graft failure greater than 1 year, but less than three years from transplant Events that cause temporary harm. Any low analysis events chosen to be escalated to a Moderate review. High (Root Cause Analysis) High level of analysis will be completed for adverse events that resulted in permanent harm. High level analysis will be performed in conjunction with the Department of Patient Safety and includes: Chronicle the Adverse Event across the Continuum of Care, Interview all staff involved and external parties relevant, Identification of root cause, underlying causes, contributing factors across the continuum of care, and analysis of related systems (infrastructure, equipment, policies, procedures, human, organizational) led by Department of Patient Safety, Identification of similar events in the past and	X 0103		

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X 0103 AKO ALI	Continued from page 42 their rate of occurrence Identification of risk points, their contribution to the Adverse Event, and possible means of prevention. These events include: Death or graft failure within one year of transplant Any near-death event Any moderate review case escalates the High Review." 2. A review of the transplant programs list of transplant surgeries completed by Transplant Surgeon (TS)2 and TS3 from their arrival to the program on 01/03/22 through present showed there were a total of 31 transplants (24 kidneys and seven livers) completed with six transplant recipients (five kidneys and one liver) brought back to the operating room (OR) post-transplant. 3. A review of the operative reports for the 5 kidney transplant recipients taken back to the OR with date, medical reason for the return and findings in OR are as follows: KTR1 Return to OR: 02/01/22 for exploratory lap	X 0103		

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X 0103 AKO ALI	Continued from page 43 and washout. Findings: Perforated colon. KTR2 Return to OR: 02/22/22 for re-exploration and repositioning of the transplanted kidney. Findings: Renal vein compression due to external iliac artery. KTR3 Return to OR: 02/22/22 for exploration. Findings: Repositioning of kidney transplant; external iliac artery compressing transplant renal vein. KTR4 Return to OR: 03/06/22 due to abnormal ultrasound reading. Findings: Normal looking kidney, perhaps compression from abdominal wall muscles. KTR5 Return to OR: 02/20/22 for compression of right kidney. Findings: Compression of right kidney and stretching of the renal vein. None of these cases were reported as an event as required by the Transplant Program's QAPI plan which states, "Non-planned returns to the OR will be reviewed for trends. These may also be reviewed as a moderate or high review case." 4. In an interview on 05/06/22 at 9:45 AM, the	X 0103		

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X 0103 AKO ALI	Continued from page 44 Chief Quality Officer (CQO) stated, "they [the five kidney cases] did not come to me however, they should have. CQO stated, "I did not know about the other cases until the Department of Health (DOH) came in on 04/27/22 to do a complaint survey." Based on review of the transplant program's Quality Assessment Performance Improvement (QAPI) plan, medical record reviews, and interviews, the Adult Liver (ALI) programs staff failed to analyze an ALI post-op death with multiple returns to the Operating Room (OR) prior to discharge in compliance with their QAPI plan to determine if any process improvements were needed. Three ALI transplant cases were reviewed, Liver Transplant Recipient (LIRT)1 through LITR3 and one had to be returned to the OR post-transplant. LITR1 expired in the hospital prior to discharge. (See X103 AKO)	X 0103		

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X 0103 AKO ALI	Continued from page 45 Findings include: 1. A review of the transplant program's Quality Assessment Performance Improvement (QAPI) plan determined ALI program has a comprehensive quality plan titled, "Kidney, Pediatric Kidney, Liver and Pancreas Transplant and Living Donor Specific QAPI Plan," effective date, 03/09/20 that defines and addresses the handling of Patient Safety Events, Incidents Serious Events and Sentinel Events. The plan states, 'Per hospital policy, A-09 HAM Patient Safety Event Reporting, a Patient Safety Event Report or Great Catch for Patient Safety card shall be completed immediately or within 24 hours of identification. Events reported via a Great Catch for Patient Safety card will be entered into the Electronic Patient Safety Event Reporting System (EPSEFS) (Midas) on the next business day. Should the EPSEFS be unavailable, the Great Catch for Patient Safety cards should be utilized ... Transplant specific adverse events may require	X 0103		

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X 0103 AKO ALI	Continued from page 46 reporting to regulatory bodies including OPTN/UNOS or CMS ... Per hospital policy, A-09 HAM Patient Safety Event Reporting, a Patient Safety Event Report or Great Catch for Patient Safety card shall be completed immediately or within 24 hours of identification. Events reported via a Great Catch for Patient Safety card will be entered into the Electronic Patient Safety Event Reporting System (EPSEFS) (Midas) on the next business day. Should the EPSEFS be unavailable, the Great Catch for Patient Safety cards should be utilized. The abdominal transplant program will also use an Adverse Events collection form to identify Adverse Events that are not reported in the EPSEFS. These will include events that may not be considered adverse events by Kidney, Pediatric Kidney, Liver Pancreas Transplant and Living Donor Specific QAPI Plan the standards of the Hospital system but are something that the transplant program will capture. These will also include events that may have occurred outside of our medical system.	X 0103		

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X 0103 AKO ALI	Continued from page 47 Reporting & Analysis Once an event has been identified, it will be reported to the QAPI Analyst for transplant. The QAPI analyst will then determine if the event took place under the control of Penn State Health Milton S. Hershey Medical Center or its outpatient sites. If yes, then the event can be entered into Midas by either the QAPI Analyst or the clinical professional who reported the Adverse Event... If the event did not occur at Penn State Health Milton S. Hershey Medical Center, the event is not entered into the Midas system. The event will be investigated the same as above by the QAPI Analyst. The event will be added to the Adverse Event Log and analyzed as below. Any investigation will be done by the Abdominal Transplant Team. Once an event has been reported, it will be reviewed and assigned a harm score. The harm scores and their level of analysis are as follows. 1. Unsafe Conditions - Low	X 0103		

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X 0103 AKO ALI	Continued from page 48 2. Event, No Harm - Low 3. Event, Harm - Moderate to High 4.nEvent, Death - High Components of a Thorough Analysis - Low Low level of analysis will be completed for adverse events with no resulted or expected patient harm. Low level analysis includes: Determining the relevance of adverse event for transplant patients. If relevant, an investigative report will be completed. These events will be reviewed for trends. Events can be escalated to a moderate analysis. These will include: "No Harm" events "Near Miss" events Infections will be reviewed for trends Rejection Episodes will be reviewed for trends Non-planned returns to the OR will be reviewed for trends. These may also be reviewed as a moderate or high review case. Death or graft failure greater than three years from transplant	X 0103		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
	399807	A. BLDG: __00_____ B. WING: _____	05/06/2022

NAME OF PROVIDER OR SUPPLIER:	STREET ADDRESS, CITY, STATE, ZIP CODE:
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X 0103 AKO ALI	Continued from page 49 Moderate (Apparent Cause Analysis) - Moderate level of analysis will be completed for adverse events that resulted in temporary harm and/or required prolonged hospitalization. These events will be reviewed at the monthly program M&M meeting. Presentations will have basic information only. At any time, events can be escalated to a high analysis. These will include: A patient death while on the waitlist A patient death or graft failure greater than 1 year, but less than three years from transplant Events that cause temporary harm. Any low analysis events chosen to be escalated to a Moderate review. High (Root Cause Analysis) High level of analysis will be completed for adverse events that resulted in permanent harm. High level analysis will be performed in conjunction with the Department of Patient Safety and includes: Chronicle the Adverse Event across the Continuum of Care, Interview all staff involved and external parties relevant, Identification of root cause,	X 0103		

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X 0103 AKO ALI	Continued from page 50 underlying causes, contributing factors across the continuum of care, and analysis of related systems (infrastructure, equipment, policies, procedures, human, organizational) led by Department of Patient Safety, Identification of similar events in the past and their rate of occurrence Identification of risk points, their contribution to the Adverse Event, and possible means of prevention. These events include: Death or graft failure within one year of transplant Any near-death event Any moderate review case escalates the High Review." 2. A review of the ALI program's list of transplant surgeries completed by Transplant Surgeon (TS)2 and TS3 from their arrival to the program on 01/03/22 through present showed there were a total seven liver Transplants completed. One liver transplant, LITR1 was taken back to the operating room (OR) post-transplant. 3. A review of the operative reports for LITR1 showed that he/she was taken back to the OR on	X 0103		

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X 0103 AKO ALI	Continued from page 51 three separate occasions. The reasons for the return and findings in OR were documented as follows: LITR1 Return to OR: 01/16/22 for severe coagulopathy and intra-abdominal bleeding. Findings: Compartment syndrome and coagulopathic bleeding. Second return to OR: 01/17/22 for bleeding and coagulopathy. Third return to OR: 01/26/22 Findings: Bleeding and coagulopathy. Patient died in hospital on 01/28/22 at 8:27 PM 4. In an interview on 05/06/22 at 9:45 AM, the Chief Quality Officer (CQO) stated, "I did a case review on the Liver recipient [LITR1] who died. The case came to me last Wednesday, which would have been 04/27/22. On 05/04/22 we did a full peer review. There were seven physicians. They interviewed TS2 and then asked him/her to leave the room so they could discuss. It was determined that the patient was very sick, had a meld of 45 and was a high-risk patient, that the patient died from a	X 0103		

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X 0103 AKO ALI	Continued from page 52 cerebral bleed, and they determined the death was not a direct result of the transplant. We did not do a Root Cause Analysis (RCA), we did a peer review."	X 0103		
X 0149 AKO ALI		X 0149		

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X 0149 AKO ALI	Continued from page 53 482.102 PATIENT AND LIVING DONOR RIGHTS 482.102 Condition of Participation: Patient and Living Donor Rights. In addition to meeting the condition of participation "Patients Rights" requirements at §482.13, the transplant program must protect and promote each transplant patient's and living donor's rights. This REQUIREMENT is not met as evidenced by:	X 0149	Plan for correction: - On 6/9/2022, the Solid Organ Transplant Quality Manager educated the Adult Kidney Only transplant surgeons regarding identification of high-risk offers in UNET; the proper completion of the Informed Consent process which included multiple discussions with the transplant candidate at different points in time; and proper completion of the current Informed Consent form to include marking the type and risk level of organ being offered to the transplant candidate prior to surgery. - On 6/9/2022, the Director of Solid Organ Transplant reviewed with the abdominal transplant surgeons the requirement of consenting for high-risk organs including marking the type and risk level of an organ being offered to the transplant candidate prior to surgery. Monitoring/tracking procedures: - Effective immediately, the Quality Associate will monitor all	Completion Date: **06/15/2022** Status: **APPROVED** Date: **09/01/2022**

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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X 0149 AKO ALI	Continued from page 54	X 0149	abdominal transplant Informed Consents on an ongoing basis and document compliance on the program's QAPI dashboard (see attachment A). The QAPI dashboard will be reviewed at each QAPI meeting. Any non-compliance will be addressed by the Solid Organ Transplant Quality Manager with the individual responsible for completing the Informed Consent. Continued non-compliance will be escalated to the Director of Solid Organ Transplant for referral to the Chief Medical Officer for Medical Staff action. Individual Responsible for the Plan of Correction: The Director of Solid Organ Transplant Corrective actions completion date: 6/15/2022 with continued monitoring b. Based on record review, document review, policy review, and staff interview, it was determined the ALI program's staff did not implement an Informed Consent process regarding informing the	

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X 0149 AKO ALI	Continued from page 55	X 0149	potential recipient about the condition of the organ being offered for their transplant, prior to the transplant surgery. This lack of action did not fully protect and promote the patient's rights. In a sample of six medical records, KTR1 through KTR5 and LITR1, one was deficient, (LITR1). Plan for correction: - On 6/9/2022, the Solid Organ Transplant Quality Manager educated the Adult Liver transplant surgeons regarding identification of high-risk offers in UNET; the proper completion of the Informed Consent process which included multiple discussions with the transplant candidate at different points in time; and proper completion of the current Informed Consent form to include marking the type and risk level of organ being offered to the transplant candidate prior to surgery. - On 6/9/2022, the Director of Solid Organ Transplant reviewed	

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X 0149 AKO ALI	Continued from page 56	X 0149	with the abdominal transplant surgeons the requirement of consenting for high-risk organs including marking the type and risk level of an organ being offered to the transplant candidate prior to surgery. Monitoring/tracking procedures: - Effective immediately, the Quality Associate will monitor all abdominal transplant Informed Consents on an ongoing basis and document compliance on the program's QAPI dashboard (see attachment A). The QAPI dashboard will be reviewed at each QAPI meeting. Any non-compliance will be addressed by the Solid Organ Transplant Quality Manager with the individual responsible for completing the Informed Consent. Continued non-compliance will be escalated to the Director of Solid Organ Transplant for referral to the Chief Medical Officer for Medical Staff action. Individual Responsible for the Plan of Correction: The Director of Solid Organ Transplant	

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X 0149 AKO ALI	Continued from page 57	X 0149	Corrective actions completion date: 6/15/2022 with continued monitoring	

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X 0149 AKO ALI	Continued from page 58 Based on record review, document review, policy review, and staff interview, it was determined the Adult Kidney Only (AKO) program's staff did not implement an informed consent process regarding informing the potential recipient about the condition of the organ being offered for their transplant, prior to the transplant surgery. This lack of action did not fully protect and promote the patient's rights. In a sample of five AKO medical records, Kidney Transplant Recipient (KTR)1 through KTR5, one was deficient, (KTR5). Findings include: 1. A review on 05/06/22 of medical record KTR5 for the AKO program showed no documented evidence to support the recipient's rights were protected. KTR5 was not informed about the organ being offered for transplant prior to transplant surgery. Specifically, the organ donor risk factors or potential medical risks that could affect the graft, the success of the transplant, or the potential for contacting an infectious disease. Reference tags X154 and X156 for specific record findings, policy review, and staff interview. Based on record review, document review, policy review, and staff interview, it was determined the Adult Liver (ALI)	X 0149		

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X 0149 AKO ALI	Continued from page 59 program's staff did not implement an informed consent process regarding informing the potential recipient about the condition of the organ being offered for their transplant, prior to the transplant surgery. This lack of action did not fully protect and promote the patient's rights. In a sample of three ALI medical records reviewed, Liver Transplant Recipient (LITR)1 through LITR3, one was deficient, (LITR1). Findings: 1. A review on 05/06/22 of medical record LITR1 for the ALI program showed no documented evidence to support the recipient's rights were protected. LITR1 was not informed about the organ being offered for transplant prior to transplant surgery. Specifically, the organ donor risk factors or potential medical risks that could affect the graft, the success of the transplant, or the potential for contacting an infectious disease. Reference tags X154 and X156 for specific record findings, policy review, and staff interview.	X 0149		
X 0154 AKO ALI		X 0154		

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X 0154 AKO ALI	Continued from page 60 482.102(a)(4) PATIENT INFORMED OF POTENTIAL RISKS 482.102(a)(4) Each patient is informed of potential medical or psychosocial risks. This REQUIREMENT is not met as evidenced by:	X 0154	Plan for correction: - On 6/9/2022, the Solid Organ Transplant Quality Manager educated the Adult Kidney Only transplant surgeons regarding identification of high-risk offers in UNET; the proper completion of the Informed Consent process which included multiple discussions with the transplant candidate at different points in time; and proper completion of the current Informed Consent form to include marking the type and risk level of organ being offered to the transplant candidate prior to surgery. - On 6/9/2022, the Director of Solid Organ Transplant reviewed with the abdominal transplant surgeons the requirement of consenting for high-risk organs including marking the type and risk level of an organ being offered to the transplant candidate prior to surgery. Monitoring/tracking procedures: - Effective 6/15/2022, the Quality Associate will update the quality	Completion Date: **06/15/2022** Status: **APPROVED** Date: **09/01/2022**

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X 0154 AKO ALI	Continued from page 61	X 0154	dashboard to include metrics for Informed Consents (see attachment A). The Quality Associate will perform monthly audits and document compliance on the program's QAPI dashboard. These audits will include documentation at the following four points in time: 1. Patient education of high-risk organ donors 2. Signed evaluation consent (Patient Acknowledgement for Transplantation) including discussion of PHS high-risk organs at the time of evaluation 3. Informed consent for PHS high-risk organ obtained prior to surgery. 4. Surgeon's pre- or post-operative note that consent for a high-risk organ was obtained prior to surgery. - The QAPI dashboard will be reviewed at each QAPI meeting. Any non-compliance will be addressed by the Solid Organ Transplant Quality Manager with the individual responsible for completing the Informed Consent. Continued	

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X 0154 AKO ALI	Continued from page 62	X 0154	non-compliance will be escalated to the Director of Solid Organ Transplant for further action and then follow medical staff process for incomplete documentation which includes escalation to the Department Chair and Chief Medical Officer. Refusal to follow medical staff and hospital policies around informed consent will be escalated through our medical staff professionalism policy which includes a stepwise approach to reporting, initial review of the concern, notification of the practitioner and eventual intervention. The intervention may include a performance improvement plan and referral to the medical staff executive committee for medical staff action. The MEC would review the issue under the Medical Staff Credentials policy if there is refusal to cooperate with the performance improvement plan. Individual Responsible for the Plan of Correction: The Director of Solid Organ Transplant Corrective actions completion date:	

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X 0154 AKO ALI	Continued from page 63	X 0154	6/15/2022 with continued monitoring Plan for correction: - On 6/9/2022, the Solid Organ Transplant Quality Manager educated the Adult Liver transplant surgeons regarding identification of high-risk offers in UNET; the proper completion of the Informed Consent process which included multiple discussions with the transplant candidate at different points in time; and proper completion of the current Informed Consent form to include marking the type and risk level of organ being offered to the transplant candidate prior to surgery. - On 6/9/2022, the Director of Solid Organ Transplant reviewed with the abdominal transplant surgeons the requirement of consenting for high-risk organs including marking the type and risk level of an organ being offered to the transplant candidate prior to surgery. Monitoring/tracking procedures:	

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X 0154 AKO ALI	Continued from page 64	X 0154	- Effective 6/15/2022, the Quality Associate will update the quality dashboard to include metrics for Informed Consents (see attachment A). The Quality Associate will audit on an ongoing basis and document compliance on the program's QAPI dashboard. This audit will include documentation at the following four points in time: 1. Patient education of high-risk organ donors 2. Signed evaluation consent (Patient Acknowledgement for Transplantation) including discussion of PHS high-risk organs at the time of evaluation 3. Informed consent for PHS high-risk organ obtained prior to surgery. 4. Surgeon's pre- or post-operative note that consent for a high-risk organ was obtained prior to surgery. - The QAPI dashboard will be reviewed at each QAPI meeting. Any non-compliance will be addressed by the Solid Organ Transplant Quality Manager with the individual	

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MILTON S HERSHEY MEDICAL CENTER - TRANSPLANT CENTER STATE LICENSE NUMBER: **P6IG0101**	**500 UNIVERSITY DRIVE, P. O. BOX 850 HERSHEY, PA 17033**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED 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	(X5) COMPLETE DATE
X 0154 AKO ALI	Continued from page 65	X 0154	responsible for completing the Informed Consent. Continued non-compliance will be escalated to the Director of Solid Organ Transplant for further action and then follow medical staff process for incomplete documentation which includes escalation to the Department Chair and Chief Medical Officer. Refusal to follow medical staff and hospital policies around informed consent will be escalated through our medical staff professionalism policy which includes a stepwise approach to reporting, initial review of the concern, notification of the practitioner and eventual intervention. The intervention may include a performance improvement plan and referral to the medical staff executive committee for medical staff action. The MEC would review the issue under the Medical Staff Credentials policy if there is refusal to cooperate with the performance improvement plan. Individual Responsible for the Plan of Correction: The Director of Solid	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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X 0154 AKO ALI	Continued from page 66	X 0154	Organ Transplant Corrective actions completion date: 6/15/2022 with continued monitoring	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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X 0154 AKO ALI	Continued from page 67 Based on record review, document review, policy review, and staff interview, it was determined the Adult Kidney Only (AKO) program's staff had no evidence documented that a high-risk organ was being offered to the intended recipient as part of the informed consent process prior to surgery. In a sample of five AKO records reviewed, Kidney Transplant Recipient (KTR)1 through KTR5, one was deficient, (KTR5). Findings include: 1. A review on 05/06/22 of KTR5's medical record showed there was no evidence documented that the intended recipient was informed, prior to the transplant surgery that the organ being offered for their transplant was a high-risk kidney. CMS expects the informed consent process involve multiple discussions with the transplant candidate at different points in time as the candidate's conditions and/or opinions may change e.g., prior to being placed on the waiting list and prior to surgery. 2. A review on 05/06/22 of KTR5's, "Consent for Living/Deceased Kidney Transplant" form, there was nothing marked for the type of organ being offered to the transplant candidate prior to surgery. 3. During a review on 05/06/22 of the AKO program's policies, it was determined that no policy related to informed consent prior to transplant was provided.	X 0154		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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X 0154 AKO ALI	Continued from page 68 However, in review of the transplant program's policy, "Organ ABO Verification in the OR prior to Transplantation," dated 02/21/22 stated, "RELATED DOCUMENTS AND REFERENCES ... OPTN Policy 5: Organ Offers, Acceptance, and Verification." The AKO program refers to the OPTN's policy, "OPTN Policy 5: Organ Offers, Acceptance, and Verification," effective date: 04/28/22 stated, "15.3 Informed Consent of Transmissible Disease Risk 15.3.A General Risks of Potential Malignancy or Disease Transmission Transplant programs must inform candidates of the general risks of potential transmission of malignancies and disease from organ donors ... The transplant program must do both of the following: 1. Explain these risks and obtain informed consent from the candidate or candidate's agent any time prior to transplant. 2. Document consent in the candidate's medical record. 15.3.B Donors with Risk Identified Pre-Transplant. Transplant programs must meet the requirements according to Table 15-1 below when the deceased or living donor has risk of disease transmission identified pre-transplant. Each time any of the following occurs: The donor tests positive for any of the following: a. Hepatitis B surface antigen (HBsAg) b. Hepatitis B nucleic acid test (NAT) c. Hepatitis C NAT The donor tests positive for HIV antibody (anti-HIV), HIV antigen/antibody (Ag/Ab), or HIV NAT, and the transplant hospital participates in an approved variance according to	X 0154		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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X 0154 AKO ALI	Continued from page 69 Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors. Then transplant programs must do all the following: 1. Explain the risks and obtain informed consent from the intended recipient or the intended recipient's agent after the organ offer but before transplant. 2. Document this consent in the intended recipient's medical record. 3. Follow the recipient for the development of potential donor-derived disease after transplant. The donor has any risk criteria for acute HIV, HBV, or HCV infection according to the U.S. Public Health Service (PHS) Guideline. Then transplant programs must do all the following: 1. Inform the intended recipient or the intended recipient's agent after the organ offer but before transplant that risk criteria are present in the donor. 2. Document that this information was provided in the intended recipient's medical record ... 15.3.C Required Post-Transplant Infectious Disease Testing 1. Transplant programs must test all recipients post-transplant for: a. HIV ribonucleic acid (RNA) by nucleic acid test (NAT) b. HBV deoxyribonucleic acid (DNA) by nucleic acid test	X 0154		

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X 0154 AKO ALI	Continued from page 70 (NAT) c. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) 2. Testing must be performed on the recipient at least 28 days but no later than 56 days post-transplant." In an interview on 05/06/22 at 2:50 PM, with the Anonymous Transplant Staff (ATS)1 stated that he/she knows of at least two recipients that have received high-risk organs without being properly consented prior to transplant by the transplant surgeon. This involved the AKO recipient described above and one Adult Liver Only (ALI) recipient (see ALI X154). Based on record review, document review, policy review, and staff interview, it was determined the Adult Liver (ALI) program's staff had no evidence documented that a high-risk organ was being offered to the intended recipient as part of the informed consent process prior to surgery. In a sample of three ALI records reviewed, LITR1 through LITR3, one was deficient, (LITR1). Findings include: 1. A review on 05/06/22 of LITR1's medical record showed there was no evidence documented that the intended recipient was informed, prior to the transplant surgery that	X 0154		

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X 0154 AKO ALI	Continued from page 71 the organ being offered for their transplant was a high-risk liver. LITR1 did recall signing the Liver Pre-Transplant High Risk Acceptance Form at the time of evaluation. However, LITR1 was not informed during the transplant surgery consent process prior to the surgery that the organ being offered was an increased risk liver. CMS expects the informed consent process involve multiple discussions with the transplant candidate at different points in time as the candidate's conditions and/or opinions may change e.g., prior to being placed on the waiting list and prior to surgery. 2. A chart entry reviewed on 05/06/22 in LITR1's medical record, "Patient Notes" section dated, 03/29/22 at 12:10 PM stated, "Spoke with pt [patient] re [reference] whether [he/she] was informed, at the time of [his/her] liver donor offer, the donor was classified as an increased Risk Donor. The patient does not remember having been informed of this by the coordinator who contacted [him/her] with the liver organ offer. [He/she] does recall signing the Liver Pre-Transplant High Risk Acceptance Form but, [he/she] is certain that [he/she] was not informed of the classification of the donor as increased risk at time of offer." 3. A review on 05/06/22 of LITR1's, "Consent for Living/Deceased Liver Transplant" form, the "Donor Type" was marked, "Standard Deceased Liver Donor." Number six, "Public Health Service (PHS) Donors at Risk of Acute Infection with Hepatitis B. Hepatitis C or HIV: Risk	X 0154		

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X 0154 AKO ALI	Continued from page 72 criteria may include any of the following within 30 days of recovery ... was marked, "not applicable." 4. During a review on 05/06/22 of the ALI program's policies, it was determined that no policy related to informed consent prior to transplant was provided. However, in review of the transplant program's policy, "Organ ABO Verification in the OR prior to Transplantation," dated 02/21/22 stated, "RELATED DOCUMENTS AND REFERENCES ... OPTN Policy 5: Organ Offers, Acceptance, and Verification." The ALI program refers to the OPTN's policy, "OPTN Policy 5: Organ Offers, Acceptance, and Verification," effective date: 04/28/22 stated, "15.3 Informed Consent of Transmissible Disease Risk 15.3.A General Risks of Potential Malignancy or Disease Transmission Transplant programs must inform candidates of the general risks of potential transmission of malignancies and disease from organ donors ... The transplant program must do both of the following: 1. Explain these risks and obtain informed consent from the candidate or candidate's agent any time prior to transplant. 2. Document consent in the candidate's medical record. 15.3.B Donors with Risk Identified Pre-Transplant. Transplant programs must meet the requirements according to Table 15-1 below when the deceased or living donor has risk of disease transmission identified pre-transplant. Each time any of the following occurs: The donor tests positive for any of the following: a. Hepatitis B surface antigen (HBsAg)	X 0154		

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X 0154 AKO ALI	Continued from page 73 b. Hepatitis B nucleic acid test (NAT) c. Hepatitis C NAT The donor tests positive for HIV antibody (anti-HIV), HIV antigen/antibody (Ag/Ab), or HIV NAT, and the transplant hospital participates in an approved variance according to Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors. Then transplant programs must do all the following: 1. Explain the risks and obtain informed consent from the intended recipient or the intended recipient's agent after the organ offer but before transplant. 2. Document this consent in the intended recipient's medical record. 3. Follow the recipient for the development of potential donor-derived disease after transplant. The donor has any risk criteria for acute HIV, HBV, or HCV infection according to the U.S. Public Health Service (PHS) Guideline. Then transplant programs must do all the following: 1. Inform the intended recipient or the intended recipient's agent after the organ offer but before transplant that risk criteria are present in the donor. 2. Document that this information was provided in the intended recipient's medical record ... 15.3.C Required Post-Transplant Infectious Disease	X 0154		

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X 0154 AKO ALI	Continued from page 74 Testing 1. Transplant programs must test all recipients post-transplant for: a. HIV ribonucleic acid (RNA) by nucleic acid test (NAT) b. HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT) c. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) 2. Testing must be performed on the recipient at least 28 days but no later than 56 days post-transplant." It was only during the transplant program's request for LITR1 to have his/her post-transplant high-risk labs drawn did the recipient learn that he/she had received a high-risk organ. In an interview on 05/06/22 at 2:50 PM, with the Anonymous Transplant Staff (ATS)1 stated that he/she knows of at least two recipients that have received high-risk organs without being properly consented prior to transplant by the transplant surgeon. This involved the ALI recipient described above and one Adult Kidney Only (AKO) recipient (see AKO X154).	X 0154		

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X 0156 AKO ALI		X 0156		

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X 0156 AKO ALI	Continued from page 76 482.102(a)(6) PATIENT INFORMED OF DONOR RISK FACTORS 482.102(a)(6) Each patient is informed of organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor. This REQUIREMENT is not met as evidenced by:	X 0156	Plan for correction: - On 6/9/2022, the Solid Organ Transplant Quality Manager educated the Adult Kidney Only transplant surgeons regarding identification of high-risk offers in UNET; the proper completion of the Informed Consent process which included multiple discussions with the transplant candidate at different points in time; and proper completion of the current Informed Consent form to include marking the type and risk level of organ being offered to the transplant candidate prior to surgery. - On 6/9/2022, the Director of Solid Organ Transplant reviewed with the abdominal transplant surgeons the requirement of consenting for high-risk organs including marking the type and risk level of an organ being offered to the transplant candidate prior to surgery. Monitoring/tracking procedures: - Effective 6/15/2022, the Quality Associate will update the quality	Completion Date: **06/15/2022** Status: **APPROVED** Date: **09/01/2022**

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X 0156 AKO ALI	Continued from page 77	X 0156	dashboard to include metrics for Informed Consents (see attachment A). The Quality Associate will audit on an ongoing basis and document compliance on the program's QAPI dashboard. This audit will include documentation at the following four points in time: 1. Patient education of high-risk organ donors 2. Signed evaluation consent (Patient Acknowledgement for Transplantation) including discussion of PHS high-risk organs at the time of evaluation 3. Informed consent for PHS high-risk organ obtained prior to surgery. 4. Surgeon's pre- or post-operative note that consent for a high-risk organ was obtained prior to surgery. - The QAPI dashboard will be reviewed at each QAPI meeting. Any non-compliance will be addressed by the Solid Organ Transplant Quality Manager with the individual responsible for completing the Informed Consent. Continued	

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X 0156 AKO ALI	Continued from page 78	X 0156	non-compliance will be escalated to the Director of Solid Organ Transplant for further action and then follow medical staff process for incomplete documentation which includes escalation to the Department Chair and Chief Medical Officer. Refusal to follow medical staff and hospital policies around informed consent will be escalated through our medical staff professionalism policy which includes a stepwise approach to reporting, initial review of the concern, notification of the practitioner and eventual intervention. The intervention may include a performance improvement plan and referral to the medical staff executive committee for medical staff action. The MEC would review the issue under the Medical Staff Credentials policy if there is refusal to cooperate with the performance improvement plan. Individual Responsible for the Plan of Correction: The Director of Solid Organ Transplant Corrective actions completion date:	

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X 0156 AKO ALI	Continued from page 79	X 0156	6/15/2022 with continued monitoring Plan for correction: - On 6/9/2022, the Solid Organ Transplant Quality Manager educated the Adult Liver transplant surgeons regarding identification of high-risk offers in UNET; the proper completion of the Informed Consent process which included multiple discussions with the transplant candidate at different points in time; and proper completion of the current Informed Consent form to include marking the type and risk level of organ being offered to the transplant candidate prior to surgery. - On 6/9/2022, the Director of Solid Organ Transplant reviewed with the abdominal transplant surgeons the requirement of consenting for high-risk organs including marking the type and risk level of an organ being offered to the transplant candidate prior to surgery.	

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X 0156 AKO ALI	Continued from page 80	X 0156	Monitoring/tracking procedures: - Effective 6/15/2022, the Quality Associate will update the quality dashboard to include metrics for Informed Consents (see attachment A). The Quality Associate will audit on an ongoing basis and document compliance on the program's QAPI dashboard. This audit will include documentation at the following four points in time: 1. Patient education of high-risk organ donors 2. Signed evaluation consent (Patient Acknowledgement for Transplantation) including discussion of PHS high-risk organs at the time of evaluation 3. Informed consent for PHS high-risk organ obtained prior to surgery. 4. Surgeon's pre- or post-operative note that consent for a high-risk organ was obtained prior to surgery. - The QAPI dashboard will be reviewed at each QAPI meeting. Any non-compliance will be addressed by the Solid Organ Transplant Quality	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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NAME OF PROVIDER OR SUPPLIER:	STREET ADDRESS, CITY, STATE, ZIP CODE:
MILTON S HERSHEY MEDICAL CENTER - TRANSPLANT CENTER STATE LICENSE NUMBER: **P6IG0101**	**500 UNIVERSITY DRIVE, P. O. BOX 850 HERSHEY, PA 17033**

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X 0156 AKO ALI	Continued from page 81	X 0156	Manager with the individual responsible for completing the Informed Consent. Continued non-compliance will be escalated to the Director of Solid Organ Transplant for further action and then follow medical staff process for incomplete documentation which includes escalation to the Department Chair and Chief Medical Officer. Refusal to follow medical staff and hospital policies around informed consent will be escalated through our medical staff professionalism policy which includes a stepwise approach to reporting, initial review of the concern, notification of the practitioner and eventual intervention. The intervention may include a performance improvement plan and referral to the medical staff executive committee for medical staff action. The MEC would review the issue under the Medical Staff Credentials policy if there is refusal to cooperate with the performance improvement plan. Individual Responsible for the Plan	

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X 0156 AKO ALI	Continued from page 82	X 0156	of Correction: The Director of Solid Organ Transplant Corrective actions completion date: 6/15/2022 with continued monitoring	

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X 0156 AKO ALI	Continued from page 83 Based on record review, document review, policy review, and staff interview, it was determined the Adult Kidney Only (AKO) program's staff had no evidence documented that a high-risk organ was being offered to the intended recipient as part of the informed consent process prior to surgery. In a sample of five AKO records, Kidney Transplant Recipient (KTR)1 through KTR5, one was deficient, (KTR5). Findings include: 1. A review on 05/06/22 of KTR5's medical record showed there was no evidence documented that the intended recipient was informed, prior to the transplant surgery that the organ being offered for their transplant was a high-risk kidney. Even though the risk is relatively low, a high-risk organ could affect the success of the graft, leading to greater risk of organ rejection, and a potential for the recipient to contract a disease should the organ be infected. CMS expects the informed consent process involve multiple discussions with the transplant candidate at different points in time as the candidate's conditions and/or opinions may change e.g., prior to being placed on the waiting list and prior to surgery. 2. A review on 05/06/22 of KTR5's, "Consent for Living/Deceased Kidney Transplant" form, there was nothing marked for the type of organ being offered to the transplant candidate prior to surgery. KTR5's surgery was	X 0156		

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X 0156 AKO ALI	Continued from page 84 on 02/10/22. An addendum by Transplant Surgeon (TS)3 was added to the medical record on 03/15/22 at 8:18 PM, Eastern Daylight Time (EDT) stating, "Of note, a part of the consent included discussion regarding the fact that this kidney was from a donor with recent [Inter Venous Drug Addict] IVDA, which made them high risk. Patient was aware and still wanted to proceed with the transplant. There was no documentation as evidence to support that KTR5 was informed of this risk prior to surgery. 3. During a review on 05/06/22 of the AKO program's policies, it was determined that no policy related to informed consent prior to transplant was provided. However, in review of the transplant program's policy, "Organ ABO Verification in the OR prior to Transplantation," dated 02/21/22 stated, "RELATED DOCUMENTS AND REFERENCES ... OPTN Policy 5: Organ Offers, Acceptance, and Verification." The AKO program refers to the OPTN's policy, "OPTN Policy 5: Organ Offers, Acceptance, and Verification," effective date: 04/28/22 stated, "15.3 Informed Consent of Transmissible Disease Risk 15.3.A General Risks of Potential Malignancy or Disease Transmission Transplant programs must inform candidates of the general risks of potential transmission of malignancies and disease from organ donors ... The transplant program must do both of the following: 1. Explain these risks and obtain informed consent from the candidate or candidate's agent any time prior to transplant. 2. Document consent in the candidate's	X 0156		

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X 0156 AKO ALI	Continued from page 85	X 0156		

medical record. 15.3.B Donors with Risk Identified Pre-Transplant. Transplant programs must meet the requirements according to Table 15-1 below when the deceased or living donor has risk of disease transmission identified pre-transplant. Each time any of the following occurs: The donor tests positive for any of the following:
a. Hepatitis B surface antigen (HBsAg)
b. Hepatitis B nucleic acid test (NAT)
c. Hepatitis C NAT

The donor tests positive for HIV antibody (anti-HIV), HIV antigen/antibody (Ag/Ab), or HIV NAT, and the transplant hospital participates in an approved variance according to Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors.

Then transplant programs must do all the following:
1. Explain the risks and obtain informed consent from the intended recipient or the intended recipient's agent after the organ offer but before transplant.
2. Document this consent in the intended recipient's medical record.
3. Follow the recipient for the development of potential donor-derived disease after transplant.

The donor has any risk criteria for acute HIV, HBV, or HCV infection according to the U.S. Public Health Service (PHS) Guideline.

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X 0156 AKO ALI	Continued from page 86 Then transplant programs must do all the following: 1. Inform the intended recipient or the intended recipient's agent after the organ offer but before transplant that risk criteria are present in the donor. 2. Document that this information was provided in the intended recipient's medical record ... 15.3.C Required Post-Transplant Infectious Disease Testing 1. Transplant programs must test all recipients post-transplant for: a. HIV ribonucleic acid (RNA) by nucleic acid test (NAT) b. HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT) c. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) 2. Testing must be performed on the recipient at least 28 days but no later than 56 days post-transplant." In an interview on 05/06/22 at 2:50 PM, with the Anonymous Transplant Staff (ATS)1 stated that he/she knows of at least two recipients that have received high-risk organs without being properly consented prior to transplant by the transplant surgeon. This involved the AKO recipient described above and one Adult Liver Only (ALI) recipient (see ALI X154).	X 0156		

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X 0156 AKO ALI	Continued from page 87 Based on record review, document review, policy review, and staff interview, it was determined the Adult Liver (ALI) program's staff had no evidence documented that a high-risk organ was being offered to the intended recipient as part of the informed consent process prior to surgery. In a sample of three ALI records reviewed, Liver Transplant Recipient (LITR)1 through LITR3, one was deficient (LITR1). Findings include: 1. A review on 05/06/22 of LITR1's medical record showed there was no evidence documented that the intended recipient was informed, prior to the transplant surgery that the organ being offered for their transplant was a high-risk liver. LITR1 did recall signing the Liver Pre-Transplant High Risk Acceptance Form at the time of evaluation. However, LITR1 was not informed during the transplant surgery consent process prior to the surgery that the organ being offered was an increased risk liver. Even though the risk is relatively low, a high-risk organ could affect the success of the graft, leading to greater risk of organ rejection, and a potential for the recipient to contract a disease should the organ be infected. CMS expects the informed consent process involve multiple discussions with the transplant candidate at different points in time as the candidate's conditions and/or opinions may change e.g., prior to being placed on the waiting list and prior to surgery.	X 0156		

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X 0156 AKO ALI	Continued from page 88 2. A chart entry review on 05/06/22 in LITR1's medical record, "Patient Notes" section dated, 03/29/22 at 12:10 PM stated, "Spoke with pt [patient] re [reference] whether [he/she] was informed, at the time of [his/her] liver donor offer, the donor was classified as an increased Risk Donor. The patient does not remember having been informed of this by the coordinator who contacted [him/her] with the liver organ offer. [He/she] does recall signing the Liver Pre-Transplant High Risk Acceptance Form but, [he/she] is certain that [he/she] was not informed of the classification of the donor as increased risk at time of offer." 3. A review on 05/06/22 of LITR1's, "Consent for Living/Deceased Liver Transplant" form, the "Donor Type" was marked, "Standard Deceased Liver Donor." Number six, "Public Health Service (PHS) Donors at Risk of Acute Infection with Hepatitis B. Hepatitis C or HIV: Risk criteria may include any of the following within 30 days of recovery ... was marked, "not applicable." 4. During a review on 05/06/22 of the ALI program's policies, it was determined that no policy related to informed consent prior to transplant was provided. However, in review of the transplant program's policy, "Organ ABO Verification in the OR prior to Transplantation," dated 02/21/22 stated, "RELATED DOCUMENTS AND REFERENCES ... OPTN Policy 5: Organ Offers, Acceptance, and Verification." The ALI	X 0156		

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X 0156 AKO ALI	Continued from page 89 program refers to the OPTN's policy, "OPTN Policy 5: Organ Offers, Acceptance, and Verification," effective date: 04/28/22 stated, "15.3 Informed Consent of Transmissible Disease Risk 15.3.A General Risks of Potential Malignancy or Disease Transmission Transplant programs must inform candidates of the general risks of potential transmission of malignancies and disease from organ donors ... The transplant program must do both of the following: 1. Explain these risks and obtain informed consent from the candidate or candidate's agent any time prior to transplant. 2. Document consent in the candidate's medical record. 15.3.B Donors with Risk Identified Pre-Transplant. Transplant programs must meet the requirements according to Table 15-1 below when the deceased or living donor has risk of disease transmission identified pre-transplant. Each time any of the following occurs: The donor tests positive for any of the following: a. Hepatitis B surface antigen (HBsAg) b. Hepatitis B nucleic acid test (NAT) c. Hepatitis C NAT The donor tests positive for HIV antibody (anti-HIV), HIV antigen/antibody (Ag/Ab), or HIV NAT, and the transplant hospital participates in an approved variance according to Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors. Then transplant programs must do all the following: 1. Explain the risks and obtain informed consent from the	X 0156		

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X 0156 AKO ALI	Continued from page 90 intended recipient or the intended recipient's agent after the organ offer but before transplant. 2. Document this consent in the intended recipient's medical record. 3. Follow the recipient for the development of potential donor-derived disease after transplant. The donor has any risk criteria for acute HIV, HBV, or HCV infection according to the U.S. Public Health Service (PHS) Guideline. Then transplant programs must do all the following: 1. Inform the intended recipient or the intended recipient's agent after the organ offer but before transplant that risk criteria are present in the donor. 2. Document that this information was provided in the intended recipient's medical record ... 15.3.C Required Post-Transplant Infectious Disease Testing 1. Transplant programs must test all recipients post-transplant for: a. HIV ribonucleic acid (RNA) by nucleic acid test (NAT) b. HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT) c. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) 2. Testing must be performed on the recipient at least 28 days but no later than 56 days post-transplant."	X 0156		

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X 0156 AKO ALI	Continued from page 91 It was only during the transplant programs request of the LITR1 to have his/her post-transplant high-risk labs drawn did the recipient learn that he/she had received a high-risk organ. In an interview on 05/06/22 at 2:50 PM, with the Anonymous Transplant Staff (ATS)1 stated that he/she knows of at least two recipients that have received high-risk organs without being properly consented prior to transplant by the transplant surgeon. This involved the ALI recipient described above and one Adult Kidney Only (AKO) recipient (see AKO X154).	X 0156		

Certified End Page

MILTON S HERSHEY MEDICAL CENTER - TRANSPLANT CENTER

STATE LICENSE NUMBER: P6IG0101

SURVEY EXIT DATE: 05/06/2022

I Certify This Document to be a True and Correct Statement of Deficiencies and Approved Facility Plan of Correction for the Above-Identified Facility Survey

Jeane Parisi
Deputy Secretary for Quality Assurance

Debra L. Bogen, MD, FAAP
Acting Secretary of Health

pennsylvania
DEPARTMENT OF HEALTH

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