DEPARTMENT OF HEALTH & HUMAN SERVICES
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Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C: 11-29-Transplant

DATE: **May 27, 2011**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Verification of Recipient and Donor Blood Type and Other Vital Data: Frequently Asked Questions and a Comparison of Requirements with the Organ Procurement and Transplantation Network

Memorandum Summary

- **Verification of Compatibility of Blood Type (ABO) and Other Vital Data:** (42 CFR 482.92) The verification of blood type and other vital data between the organ donor and recipient is currently the most frequently cited condition-level deficiency during the transplant program surveys. Since the implementation of the regulation we have received many questions related to this section of the regulation from surveyors, providers and other components involved in transplantation.
- **Frequently Asked Questions:** This memorandum addresses frequently asked questions about the Centers for Medicare & Medicaid Services (CMS) requirements for this Condition of Participation (CoP), Organ Recovery and Receipt (42 CFR 482.92), tags X071-X074. This guidance will be used by the surveyors during the transplant surveys to determine whether or not a transplant program meets the CoP requirements during the transplant surveys.
- **Comparison of Requirements:** This memorandum also describes the similarities and differences between CMS' requirements in this area as compared to the Organ Procurement and Transplantation Network (OPTN).

This memorandum provides clarification of CMS guidance to the CMS Regional Offices (ROs), State Survey Agencies (SAs), and the CMS contractor involved in the survey and certification activities of organ transplant programs related to the verification of blood type (ABO) and other vital data per CoP, Organ Recovery and Receipt (42 CFR 482.92). We have received inquiries from providers and SAs related to the difference in the CMS regulations and the OPTN requirements for ABO verification and documentation; therefore, we are providing more specific guidelines by addressing frequently asked questions and providing a comparison of the CMS regulations and the OPTN requirements for ABO verification.

Transplant Surveys

The process for conducting surveys under the CoPs will not change. Surveyors will continue to follow the survey protocol, State Operations Manual (SOM) and interpretive guidelines to review the requirements of the Medicare CoPs and determine if the facility maintains the processes and structures necessary to achieve compliance. This guidance supplements previously released information and has been reviewed and approved by the Health Resources and Services Administration, which oversees the OPTN.

Attachment 1 includes frequently asked questions for tags X072-X074. **Attachment 2** is a side by side comparison of the CMS regulation and the OPTN requirements for ABO verification which is intended to provide additional information for SAs as well as providers.

The following CMS X tags are affected by this memorandum:

X071 §482.92 Condition: Organ Recovery and Receipt
X072 Standard: Organ recovery
X073 Standard: Organ receipt
X074 Standard: Living donor transplantation

Effective date: The guidance is effective immediately. Please ensure that all appropriate staff is fully informed within 30 days of the date of the memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State and RO training coordinators.

If you have any questions or comments, please contact Michele Walton at michele.walton@cms.hhs.gov or (410) 786-3353.

/s/
Thomas E. Hamilton

Attachments (2)

cc: Survey and Certification Regional Office Management

Attachment 1: Frequently Asked Questions

Verification of ABO and Other Vital Data: Clarification of the Centers for Medicare & Medicaid Services (CMS) Interpretive Guidelines for Tags X072-X074

A.	Frequently Asked Questions: X072- Organ Recovery	
A1.	Whose verification of compatibility and signature is/are required?	A member of the transplant program's recovery team. This individual is not specified in regulation.
A2.	What is required?	1. Written evidence the verification occurred (e.g., notations of the compatibility of the donor/recipient blood type and other vital data). 2. Signature of the transplant program's recovery team member who verified the compatibility of the donor with the intended recipient.(electronic or written) 3. Date and time of verification to support that this was done after the procurement team arrives at the donor facility and prior to organ recovery. 4. Date and time of the incision to remove the organ from the deceased donor.
A3.	Where is the verification done?	Onsite at the recovery hospital, in the operating room or organ recovery suite. This is done using documentation onsite and cannot be done via phone or remotely (e.g. internet).
A4.	Where does the verification need to be documented?	In transplant program's own medical records. The surveyors will not have access to the OPO records. Identifying that the verification is in the OPO records is not sufficient.
A5.	When should the verification occur?	• After donor is established as a donor by declaration of death; • After recovery team arrival at the donor facility; and • Prior to donor incision for organ recovery. The surveyors will review the incision time to ensure that verification for compatibility was completed within the time periods above. Once verification is complete the expectation is that continuous oversight of the potential donor organ verified would be maintained until donor incision.
A6.	What is compared?	The blood type and UNOS ID in the donor's original medical records compared with onsite written evidence of the intended recipient's information (e.g., the DonorNet match run for potential recipients'/UNet). The verification would also include any other donor/recipient compatibility elements that the transplant

		program has identified in its own protocols will be verified. Calling back to the hospital for the recipient's information for compatibility is not acceptable.
A7.	Why?	This comparison will verify that the proper organ is being recovered for the correct potential transplant recipient on the match run.

*As described in *Attachment 2*, the Organ Procurement and Transplantation Network (OPTN) policies do not have requirements for verification by the transplant program prior to organ recovery from a deceased donor.

B.	Frequently Asked Questions: X073- Organ Receipt	
B1.	Whose verification of compatibility and signature is/are required?	The transplant Surgeon and another licensed health care professional; verification by 2 persons is required. The individual serving as "Another licensed health care professional" must be identified in the transplant program's policies and procedures. Please note, OPTN policy states that it is the responsibility of the transplanting surgeon at the transplant program receiving the organ offer to ensure medical suitability of donor organs for transplantation into the potential recipient, including compatibility of donor and candidate ABO blood type. OPTN policy makes no specific reference to who must sign the verification forms, however.
B2.	What is required?	The review of the patient medical record should show: (electronic or written) 1. Written evidence the verification occurred (e.g., notations of the donor/recipient blood type and other vital data); 2. Signatures dated and timed of both individuals performing the ABO and other vital data verification to include: a. Transplant surgeon; b. Another licensed heath care professional, c. If one or both individuals verified the compatibility visually (i.e., the operation was already underway), this should be clearly documented with date(s) and time(s) documented as the verification occurs during the operation. Individual(s) who visually verified the compatibility of the donor organ with the recipient prior to implantation should follow-up with corresponding signature(s) following the operation attesting to the fact that the verifications were made visually during the operation and per hospital policy. 3. Date and time of incision/implantation of the donor organ into the recipient. Note: For verification purposes, it is permissible for the program to document the incision time or anastomosis time instead of the implantation time, provided that the verification always occurs after the organ arrives in the operating room/suite, and prior to the first anastomosis.

		4. Ensure that the date(s) and time(s) of the verifications by both individuals support that verification occurred prior to implantation/first anastomosis of the donor organ. OPTN policy requires that the verification takes place after receipt and prior to first anastomosis.
B3.	Where is the verification done?	Onsite at the transplant hospital. This is done using documentation onsite and cannot be done via phone or remotely. If the organ was procured in the recipient hospital verification prior to implantation/anastomosis is still required and separate from verification prior to organ recovery. These are separate verifications.
B4.	Where does the verification need to be documented?	The verification must be recorded in the recipient's transplant program records. It is permissible for the incision/implantation/anastomosis time to be found in the operating room record.
B5.	When should the verification occur?	Prior to organ transplant (incision) or before implantation/first anastomosis in cases where the surgery is started prior to organ arrival.
B6.	What is compared?	Donor's information (blood type and UNOS ID number) outlined in the documentation arriving with the organ, or as outlined on UNet. The recipient's information (blood type and UNOS ID) would be determined from the recipient's medical record. The verification would also include any other donor/recipient compatibility elements that the transplant program has identified in its own protocols will be verified.
B7.	What if multiple organs from the same donor are being implanted into the same recipient?	CMS does not require that there is a separate form for each organ. However, presuming that the organs are being implanted at separate times and by separate teams, additional documentation would be required. The transplant surgeon for each organ and another licensed healthcare professional must complete the verification prior to implantation of that organ. As described above OPTN policy does not specify who must complete the verification.
B8.	Why?	This comparison will verify that the correct organ is being transplanted into the correct recipient.

*As described in *Attachment 2*, the Organ Procurement and Transplantation Network (OPTN) policies have similar requirements for verification prior to transplantation; any differences from CMS policy are noted.

C.	Frequently Asked Questions: X074- Living Donor Transplantation	
C1.	What programs do these regulations apply to?	This requirement applies to programs that perform living donor transplants (either directly or under contract or by agreement).
C2.	Whose verification of compatibility and signature is/are required?	Transplant surgeon and another licensed health care professional; the individual serving as "Another licensed health care professional" must be identified in the transplant program's policies/procedures.
C3.	What is required?	The review of the patient medical record should show: (electronic or written) 1 Written evidence the verification occurred (e.g., notations of the donor/recipient blood type and other vital data (UNOS ID)); 2. Signatures dated and timed of both individuals performing the ABO and other vital data verification to include: a. Transplant surgeon; b. Another licensed heath care professional. 3. Date(s) and time(s) of verification by both individuals to support that this was done prior to incision for removal/recovery of the living donor organ; and 4. Date and time of the incision for removal/recovery of the donor organ to support the verification occurred prior to incision into the potential living donor.
C4.	Where is the verification done?	Onsite at the transplant/donor hospital, where the recovery of the donor organ for the transplant takes place. This is done using documentation onsite at the time of the procedure and cannot be done in preparation for, or prior to the surgery as in the day before or via phone or remotely (e.g. internet).
C5.	Where does the verification need to be documented?	The location of the documentation can be determined by the program. Preferably, it would be in both the donor and recipients' medical records. However, it is permissible for a transplant program to have it at one location to demonstrate that the verification occurred (e.g., the recipient's medical record).
C6.	When should this verification occur?	Prior to organ recovery, prior to incision into the potential living donor.
C7.	What is compared?	The program will compare the blood type and other vital data (e.g. UNOS ID) of the living donor as

		documented in the medical record to the recipient's blood type and other vital data. The verification would also include any other donor/recipient compatibility elements that the transplant program has identified in its own protocols will be verified.
C8.	Why?	This comparison will verify that the correct organ is being recovered from the living donor for transplantation into the intended recipient.
C9.	Note:	It does not matter if the recovery of the donor organ occurs inside or outside of the hospital where the transplant is to be performed; the organ must still be verified upon arrival to the recipient's hospital or recipient operating room as described in Section 482.92(b) above at tag X073.

*As described in *Attachment 2*, the Organ Procurement and Transplantation Network (OPTN) policies do not have requirements for verification prior to organ recovery from a living donor.

Attachment 2: Verification of Blood Type (ABO) and Other Vital data:
CMS-OPTN Crosswalk of Requirements

GENERAL VERIFICATION REQUIREMENTS X071-074

	CMS	OPTN
References	42 CFR parts 482, Subpart E 488, and 498 Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants; Final Rule, Section 482.92 Condition of Participation Organ Recovery and Receipt, and Organ Transplant Surveys, Interpretive Guidelines: X Tags, Attachment A, tags 071-074	42 CFR Chapter 1 – Public Health Service, Department of Health and Human Services; Subchapter K – Health Resources Development; Part 121 – Organ Procurement and Transplantation Network; OPTN Final Rule, Section 121.4 OPTN policies: Secretarial review and appeals.
Requirement to have a written policy:	**§482.92 Condition of Participation: Organ Recovery and Receipt.** Transplant centers must have written protocols for validation of donor-recipient blood type and other vital data for the deceased organ recovery, organ receipt, and living donor organ transplantation processes. The transplanting surgeon at the transplant center is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipients.	**3.1.2 Transplant Center.** A transplant center is a hospital that is a Member in which transplants are performed. A transplant center may also be called a transplant hospital. It is the responsibility of the transplanting surgeon at the transplant center receiving the organ offer for the surgeon's candidate to ensure medical suitability of donor organs for transplantation into the potential recipient, including compatibility of donor and candidate by ABO blood type. Upon receipt of an organ, prior to implantation, the transplant center is responsible for verifying the recorded donor ABO with the recorded ABO of the intended recipient and UNOS Donor ID number. These actions must be documented and are subject to review upon audit.

VERIFICATION DURING ORGAN RECOVERY X072

A.	CMS		OPTN
Regulation/Guidelines: verification when a transplant program sends its own team to recover an organ	**CMS Regulation 42 CFR 482.92(a) Standard: Organ Recovery.** When the identity of an intended transplant recipient is known and the transplant center sends a team to recover the organ(s), the transplant center's recovery team must review and compare the donor data with the recipient	**CMS Interpretive Guidelines**: Tag 072 This standard applies when the hospital's own team recovers the organ(s). Review the transplant program written policies and procedures to verify that the program's organ recovery team must obtain, review, and compare the deceased donor's blood type and other vital data including donor identification with the intended recipient's blood type ONSITE, PRIOR TO ORGAN RECOVERY TAKING PLACE. Note: This comparison will verify that the proper organ is being recovered. The UNet^{sm} system performs a compatibility review of specific vital medical factors (e.g., ABO compatibility, HLA antigens, serology status/acceptance, age, size, etc) as part of the computerized matching process of donors for a potential recipient. The transplant program is not required to repeat this full compatibility review, but must verify that the organ being recovered is for the intended recipient that has been identified on the UNet^{sm} match list, and must verify that the donor's and intended recipient's blood type are compatible. Request a list of the instances over the past 3 years when the transplant program dispatched its own team to recover an organ. Review the transplant program's documentation for a sample of the transplant patients who received an organ recovered by the transplant program's team during that time. Confirm that the blood type and donor identification were verified onsite at the donor hospital prior to organ recovery. The location of this documentation may vary by transplant program.	OPTN does not have this requirement

		blood type and other vital data before organ recovery takes place.	Compare the dates and times of the progress notes or recovery sheet of the donor blood type and identifying information against the recipient's blood type and identifying information; and verify that this comparison was completed at the donor hospital prior to the organ recovery. Interview one of the transplant program team members that participated on an organ recovery team. Confirm that the team member is aware of the policy for validation and complies with this policy. Note: There may be teams from the OPO that do not include members of the hospital's team which go to recover an organ; these recoveries **should not** be included in this sample.	

VERIFICATION DURING ORGAN RECEIPT *(Applies to Deceased Donor Organs and Living Donor Organs that Are Transported to the Hospital)* X073

B.	CMS		OPTN
Regulation/Guidelines: verification when an organ arrives at the transplant program, even if this has been verified before.	**CMS Regulation 42 CFR 482.92 (b) Standard: Organ Receipt**. After an organ arrives at a transplant center, prior to transplantation, the transplanting surgeon and another licensed health care professional must verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient.	**CMS Interpretive Guidelines** (highlighting added for emphasis): Tag 073 Review the transplant program's policies and procedures to verify a requirement that when an organ arrives at the transplant program, a transplant surgeon and another licensed healthcare professional must verify that the donor's blood type and donor identifying information are compatible with the intended recipient prior to transplantation at the transplant program. Note: This comparison will verify that the proper organ will be transplanted. The UNet^{sm} system performs a compatibility review of specific vital medical factors (e.g., ABO compatibility, HLA antigens, serology status/acceptance, age, size, etc) as part of the computerized matching process of donors for a potential recipient. The transplant program is not required to repeat this full compatibility review, but must verify that the organ being recovered is for the intended recipient that has been identified on the UNet^{sm} match list, and must verify that the donor's and intended	**3.1.2 Transplant Center**. A transplant center is a hospital that is a Member in which transplants are performed. A transplant center may also be called a transplant hospital. It is the responsibility of the transplanting surgeon at the transplant center receiving the organ offer for the surgeon's candidate to ensure medical suitability of donor organs for transplantation into the potential recipient, including compatibility of donor and candidate by ABO blood type. Upon receipt of an organ, prior to implantation, the transplant center is responsible for verifying the recorded donor ABO with the recorded ABO of the intended recipient and UNOS Donor ID number. These actions must be documented and are subject to review upon audit.

			recipient's blood type are compatible. The transplant program's policy must specifically identify who qualifies as "another licensed healthcare professional" to verify the compatibility of blood type and donor identifying information. Review the sample of transplant recipient medical records to verify that the transplanting surgeon and the other licensed healthcare professional, as defined by the transplant program's policy, appear in each case attesting that the donor's blood type and donor identifying information were compared at the transplant program and found to be compatible with the intended recipient. The documentation outlining the donor's blood type and other vital donor identifying information must arrive with the organ at the transplant program. If the documentation is missing or incomplete, the transplanting surgeon and other licensed healthcare professional must follow-up to ensure adequate verification. Even though a transplant program's own team may recover the organ (as described in Tag X072) and verifies the blood type and donor ID	

			prior to organ recovery, the transplant program is still responsible for verifying the blood type and other vital donor identification as described under this section after the organ has arrived at the transplant program prior to transplantation. If the operation has begun and the surgeon is awaiting arrival of the donated organ, the transplant surgeon remains responsible for verifying the blood type and other vital donor identification. It is not required that the surgeon would stop the operation for this verification (given the time-sensitive nature of some transplant surgeries). He or she would be permitted to verify this information visually prior to the transplant, with explicit timed documentation of the visual verification of the data by the other health care professional. The transplant surgeon must then attest to the accuracy of this documentation following the operation. Include questions during the interviews to ensure that transplant program staffs are aware of and following the procedures.	

VERIFICATION FOR LIVING DONOR TRANSPLANTS: ***(Applies to verification of the living donor and the intended recipient prior to removal of the living donor organ)*** **X074**

C.	CMS		OPTN
Regulation/ Guidelines for: verification of the compatibility of living donors	**CMS Regulation 42 CFR 482.92 (c) Standard: Living Donor Transplantation.** If a center performs living donor transplants, the transplanting surgeon and another licensed health care professional at the center must verify that the living donor's blood type and other vital data are compatible with transplantation of the intended recipient immediately before the removal of the	**CMS Interpretive Guidelines**: Tag 074 Review the transplant program's policies and procedures (specific to living donor transplants) and verify the inclusion of language that the transplant surgeon and another licensed healthcare professional verify that the donor's blood type and other vital identifying information are compatible with the intended recipient, prior to organ recovery. Note: This comparison will verify that the proper organ is being recovered. The UNet^{sm} system performs a compatibility review of specific vital medical factors (e.g., ABO compatibility, HLA antigens, serology status/acceptance, age, size, etc) as part of the computerized matching process of donors for a potential recipient. The transplant program is not required to repeat this full compatibility review, but must verify that the organ being recovered is for the potential recipient that has been identified on the UNet^{sm} match list, and must verify that the donor's and intended recipient's blood type are compatible. The policies and procedures must also define who qualifies as "another licensed healthcare professional" who may verify the compatibility of the living donor's blood type and donor identifying information with the transplant recipient. Review the medical records of a sample of living donors to confirm that the transplanting surgeon and one other "licensed healthcare professional" verify that the donor's blood type and other vital donor identifying information were compatible with the intended recipient, PRIOR TO	OPTN requirements do not address ABO verification prior to the donor incision; however OPTN policy does require verification after receipt of the organ prior to implantation into the recipient.

	donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s).	REMOVAL of the donor organ (s) and, if applicable (i.e., organ may remain in the transplant recipient) prior to the removal of the recipient's organ(s). Include questions during the interviews to ensure that transplant program staff is aware of and following this procedure.		

RESPONSBILITY FOR TRANSPORT OF LIVING DONOR ORGANS

D.	CMS	OPTN
OPTN Policy: Responsibility for Transport of Living Donor Organs	CMS does not have this requirement or any conflicts with this requirement.	12.7 Responsibility for Transport of Living Donor Organs. The following policies address standardized packaging of living donor organs and tissue typing materials to be transported for the purposes of organ transplantation. When an organ from a living donor is procured, the Transplant Center shall be responsible for ensuring the accuracy of the donor's ABO on the container label and within the donor's documentation. The Transplant Center shall establish and implement a procedure for obtaining verification of donor ABO data by an individual other than the person initially performing the labeling and documentation requirements put forth in Policies 12.7.1 and 12.7.5. The Transplant Center shall maintain documentation that such separate verification has taken place and make such documentation available for audit. Upon receipt of an organ from a living donor and prior to implantation, the Transplant Center shall be responsible for determining the accuracy and compatibility of the donor and recipient ABO and document this verification in compliance with Policy 3.1.2.

STANDARD LABELING SPECIFICATION

E.	CMS	OPTN
OPTN Policy: Standard labeling	CMS does not have this requirement or	12.7.1 Standard Labeling Specifications. The Transplant Center shall be responsible for ensuring that the outermost surface of the transport box containing organs and/or tissue typing specimen containers has a completed standardized external organ container label (provided by the OPTN contractor). Any

Specifications	any conflicts with this requirement.	previous labels on the transport container must be removed prior to labeling the box so that only one label exists. The Transplant Center shall label each specimen within the package in accordance with policy. The transplant center is responsible for ensuring that each tissue or donor organ container that travels outside of the recovery facility is labeled appropriately. In the case of organs from living donors who remain in the same operating room suite as the intended candidate(s), the Transplant Center must develop, implement, and comply with a procedure to ensure identification of the correct donor organ for the correct recipient. The Transplant Center must document that the correct organ was identified for the correct candidate prior to transplant. Some type of donor organ labeling and documentation must be present in the candidate chart. A "time out" prior to leaving the donor operating room and an additional "time out" upon arrival in the candidate operating room is recommended. **Exception:** In the case of a single donor organ/organ segment remaining in the same operating room suite as a single intended candidate for a simultaneous transplant, donor organ labeling and "time outs" are not necessary. In the case of organs from living donors that travel outside of the recovery facility, the Transplant Center(s) involved shall be responsible for ensuring that packaging is consistent with the requirements of Policies 12.7.2 and 12.7.4, and that the outermost surface of the transport box containing the organ must have a completed standardized external organ container label (provided by OPTN Contractor). The recovering Transplant Center shall label each specimen within the package in accordance with these policies. The recovering Transplant Center is responsible for ensuring that each container that travels outside of the recovery facility is labeled appropriately.