DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C-12-19-Transplant

DATE: **March 9, 2012**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Living Donor Services Occurring in Transplant Programs Other than that of the Organ Recipient: Requirements and Surveyor Guidance

Memorandum Summary

- **Living Donors Served by a Different Program:** This letter addresses Medicare requirements for transplant programs and surveyor activities in which some or all of the services for a living donor are provided by a program other than the transplant program of the organ recipient. These can be ongoing arrangements between two hospitals or can be episodic arrangements as part of a single donation or multi-organ exchange.

- **Responsibility of Recipient Transplant Program:** The organ recipient's transplant program must have evidence of a written agreement or contract with the living donor organ program and is responsible for ensuring that certain minimum quality standards are met for each donor organ it receives.

- **Finalizes Interim Guidance, S&C 11-40-Transplant:** This memorandum replaces the interim guidance that was previously released September 30, 2011.

This memorandum replaces previously released interim guidance S&C: 11-40-Transplant.

The Medicare Conditions of Participation (CoPs) for organ transplant centers (i.e., transplant programs) at 42 CFR Part 482, Subpart E outline the minimum quality requirements that must be provided to transplant patients and living donors. (See 72 Federal Register 15198, March 30, 2007, (CMS-3835-F)).

The Centers for Medicare & Medicaid Services (CMS) is aware of several types of arrangements in which a transplant program does not directly provide services for a living donor but rather under contract or arrangement with another transplant program, receives donor organs from a separate hospital that does not provide services to the organ recipient. The guidance in this memo covers all of these types of arrangements. For example, there may be an ongoing

arrangement between two transplant programs, such as children and adult programs, or a transplant program that contracts with another program for the psychosocial and medical evaluation. There are also episodic arrangements as part of a single donation or multi-organ exchange where more than two transplant programs are "swapping" organs.

The CoPs for organ transplant programs include several provisions that apply to any program that is performing transplants with an organ from a living donor. If the services for a living donor are provided by a transplant program at another hospital, these services are considered to be provided by the recipient transplant program under contract or arrangement.[1] ***As such, the transplant program providing services to the transplant recipient is responsible for certain activities to ensure that the program is Medicare approved and that certain basic services are provided to those living donors.***

The requirements for the transplant recipient program providing living donor services under contract/arrangement and a description of CMS survey activities are further detailed below:

A. <u>Requirements for Transplant Programs that receive Living Donor Services under Contract or Arrangement</u>

A recipient's transplant program that has its living donor services provided by one or more programs under contract or arrangement on either an ongoing or episodic basis must:

1) Have written evidence of a contract or agreement with the living donor transplant program(s). This may be a specific contract or agreement between two hospitals or programs; or it may include participation in a transplant registry for paired donation of living donors and recipients.

2) Have a copy of the Medicare-approval letter for the living donor transplant program with which it has a contract or agreement; or have documented evidence that the CMS website listed below was reviewed prior to accepting the living donor organ to ensure that the program was a Medicare-approved program.

   http://www.cms.gov/CertificationandComplianc/Downloads/ApprovedTransplantPrograms.pdf

3) Retain copies of the medical records *up to the point of admission to the hospital for the donation* for any living donors whose organs were transplanted by the recipient transplant program. These records must be kept separate from the recipient's medical record. It is not expected that the medical record would include those records that occur on the day of donation such as labs and the anesthesia report. The recipient transplant program must review the records in advance of the donation to ensure the following minimum requirements are met:

   A. There is a complete medical and psychosocial evaluation in the medical record completed by the relevant professionals of a multidisciplinary team

[1] 42 C.F.R. §482.12(e) outlines the Medicare requirements for a contracted service in a hospital. A transplant program must also comply with all Hospital CoPs (42 C.F.R. §482.1 through §482.57).

which has determined that the individual is a suitable living donor. (42 CFR §482.90)

B. An Independent Living Donor Advocate (IDA) has met and worked with the potential living donor and has been included in the discussions of the potential donor's suitability. (42 CFR §482.98)

C. There is a fully-documented informed consent process in the living donor's medical record that meets the minimum Medicare requirements. (42 CFR §482.102)

Note: This is *not* an exhaustive list of the requirements that apply to living donor services. The identification of this subset does not mean that the other CoPs for living donors are waived. *This subset of CoPs is outlined because the recipient's transplant program must verify that these requirements have been met for any given living donor prior to the donation occurring.*

4) Please note, we are requiring that the receiving transplant programs perform *due diligence* to ensure that the requirements described above are met prior to accepting a living donor organ. It is not CMS' intention to establish a single standard of practice in how living donors are evaluated, provided with informed consent, or the specific activities of the independent living donor advocate. It is permissible for a transplant recipient's program to use another hospital's policies and procedures for any given living donor as long as the minimum standards described above are met. For example, if a transplant recipient program usually requires a nutritional evaluation by a dietitian for any living donor candidate with a BMI over 30, but a living donor organ is available through a "swap" where the individual has a BMI over 30, the transplant recipient hospital does not have to require a full nutritional evaluation before accepting that individual as a suitable living donor.

5) As part of the Quality Assessment and Performance Improvement (QAPI) program, ensure that there is a feedback system between the recipient and donor hospital to address any adverse events that occurs in the donor or the recipient for a specific donation or transplant.

For example, if the recipient had an adverse event that would need to be communicated to the donor hospital. If the donor had an adverse event, that would need to be communicated to the recipient hospital. The definition of an adverse event can be found at 42 CFR §482.70. It is not expected that there would be two separate root cause analyses of the adverse event, nor is it expected that the root cause analysis would be shared with the other hospital. However, there must be notification that an event has occurred and written communication between the two programs of the specific actions taken to prevent repeat incidences.

If the recipient's program does not perform *any* living donor services directly (i.e., all living donor services are contracted), the program is still expected to track objective indicators to review the quality of the contracted service; however, CMS is not requiring a specific number of or format for these indicators.

Additional Clarification:

A recipient's transplant program that *only* receives living donor organs under contract or arrangement from a program at another hospital and does not perform any living donor services directly is not expected to:

1) Develop and maintain its own written transplant program policies separately from the contracted living donor program: donor selection criteria, the donor's medical and psychosocial evaluation, and donor management policies for the donor evaluation, donation and discharge phases of living organ donation.
2) Conduct its own separate donor evaluation, informed consent process, or multidisciplinary selection committee in addition to the contracted program to determine whether or not the potential living donor is a suitable candidate.
3) Provide a separate independent living donor advocate (IDA) or living donor advocate team in addition to the IDA provided via the contracted services.

B. CMS Surveyor Guidance

In cases where a survey team is reviewing a transplant program where some or all of the living donor services are provided by a program at another hospital (i.e., under arrangement or contract), CMS surveyors would include this contracted service as part of their review (described in more detail below). In a multi-organ exchange (i.e., swap) among multiple transplant programs, surveyors will only review the specific program that provided the living donor organ for that transplant program's recipient. For example, if the multi-organ exchange involved 10 organs at seven hospitals, the surveyor would not review all seven hospitals, just the donor hospital(s) that provided the specific organ to the recipient(s) at the transplant program under review.

The protocol and specific steps surveyors would use to review this contracted service are outlined below.

Table 1: Surveyor Guidance: Surveying a Transplant Program where some/all of the Living Donor Services are Performed Elsewhere

Survey Process	Surveyor Guidance
Task 1: Pre-survey Preparation Off-site	You may not know whether living donor services are provided under contract/arrangement. If you do have this information, discuss any prior survey and certification issues of the living donor transplant program that may need to be reviewed with the team.

Task 2: Entrance Activities	Ask the recipient transplant program whether any living donor services are provided by another transplant program under contract or arrangement. If so, for which specific organ types? If the program provides living donor services under contract/arrangement, request the following items from the program: 1) Written evidence of the contract or agreement with the living donor's transplant program or evidence that the program is participating in a transplant registry for paired donation. 2) Evidence of Medicare-approval which could include either the letter granting Medicare approval or evidence that the program reviewed the CMS website prior to accepting the donor organ; and 3) A list of living donors for the past 3 years who had some/all of their services performed at another program, (including name of hospital and program, and date of donation);
Task 3: Administrative Review	<u>Hospital Contracts</u> Review the written agreement with the living donor transplant program. This may be a specific contract/agreement between two hospitals or programs, or it may include participation in a registry for paired exchanges.
Task 4: Orientation to Transplant Program Areas	Do not go onsite to the contracted living donor transplant program. If there are any concerns with the contracted program, refer the issues for a complaint survey to be performed at the contracted program.
Task 5: Observations of Care	Only observe care in the program you are surveying, do not go onsite to the contracted living donor program for observations of care. If there are any concerns with the contracted program, refer the issues for a complaint survey to be performed at the contracted program.
Task 6: Sample Selection	In your living donor sample, include individuals who received some/all of their services at another transplant program.
Task 7: Patient Interviews	Do not interview living donors who received all of their care at another transplant program. If there are any concerns refer these issues for a complaint survey of the contracted program. If the living donor received only some of their care at another transplant program, they may be included in the sample of living donor interviews.

Task 8: Review of Transplant Patient and Living Donor Medical Records	The transplant recipient's program must have a copy of the living donor's medical record up to the point of admission to the hospital for donation. The record must be separate from the recipient's medical record and be made available for the surveyor to review. Review the copy of the living donor's medical record for compliance for the following areas: • a complete medical evaluation; • a complete psychosocial evaluation; • determination of the living donor's suitability for donation; • a full informed consent; and • evidence of services provided by an Independent Living Donor Advocate, and Deficiencies in any of these areas will be cited at the appropriate tag for the survey you are conducting at the recipient's transplant program. If there are significant concerns about the living donor program's compliance with the CoPs (e.g., no living donors were assigned an Independent Living Donor Advocate, a missing or inadequate medical/psychosocial evaluation, etc.), refer these issues for a complaint survey of the contracted transplant program. As described earlier, it is not CMS' intent to establish a nationwide standard in exactly how care for living donors is provided. There may be variation in how these requirements are met between the living donor and transplant recipient's program.
Task 9: Staff Interviews	Do not interview staff at the contracted living donor's transplant program. Refer any significant concerns for a complaint survey of the contracted transplant program. Include in your interview with staff questions about the review of the living donor medical record to ensure that the minimum requirements are met.
Task 10: Personnel Record Review	Do not request or review personnel records from the contracted living donor transplant program. If there are concerns about the qualifications of personnel at the contracted living donor transplant program, refer these issues for a complaint survey of the contracted transplant program.
Task 11: QAPI Review	Review the recipient transplant program's QAPI program to ensure: 1) There is a feedback system to address any adverse events

	that occur from a donation and subsequent transplant. 2) There is notification to the recipient or donating hospital for any event that occurred and identified actions taken to prevent repeat instances. It is not expected that the transplant programs would share the analysis of the adverse event. Please note that if the program is not providing *any* living donor services directly (i.e., all living donor activities are contracted), the QAPI activities, objective indicators tracked and performance improvement projects can be different than if they were providing them directly. However, it must still be addressed within the QAPI plan. For example, instead of the transplant program tracking all quality indicators directly, the QAPI plan may include a review of the living donor program's indicators and a requirement for the donor's program to develop of a plan to address any poor indicators. Cite any deficiencies identified under the appropriate tags for the survey you are conducting at the recipient transplant program.
Task 12: Pre-exit	No change in surveyor activities.
Task 13: Exit Conference	Discuss with the organ recipient's transplant program any findings related to living donor services. (Note: The program is expected to share these findings with the contracted living donor transplant program.)
Task 14: Post Survey Activities	The CMS-2567 must include any findings related to the provision of living donor services (including those provided by a contracted living donor transplant program). The plan of correction submitted by the recipient transplant program must address how these areas will be corrected.

Please send any comments or questions you may have about this guidance to Karen Tritz at Karen.Tritz@cms.hhs.gov.

Effective Date: The guidance is effective May 1, 2012. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

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

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management