

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C: 11-40-Transplant

DATE: September 30, 2011

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 Interim 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.

A. Policy Background

The Medicare Conditions of Participation (CoPs) for organ transplant centers (i.e., transplant programs) at 42 C.F.R. 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 at 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 and must ensure that the program providing living donor services is Medicare approved and meets basic requirements.*** The requirements for the transplant recipient program providing living donor services under contract/arrangement and a description of CMS survey activities are discussed in more detail below:

B. Requirements for Transplant Programs that receive Living Donor Services under Contract or Arrangement

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) outlining the scope of the services and the process to 1) review the policies and procedures related to: donor evaluation and selection, informed consent, and multidisciplinary donor management throughout the phases of donation; and 2) to monitor and evaluate these services.
- 2) Have a copy of the Medicare-approval letter for the living donor transplant program with which it has a contract or agreement.
- 3) Retain copies of the medical records of any living donors whose organs were transplanted by the recipient transplant program *up to the point at which the donation occurs*. The recipient transplant program must review these records in advance of the transplant to ensure the following CoPs are met:
 - A) There is a complete medical and psychosocial evaluation in the medical record which indicates that there is a comprehensive evaluation and that a multidisciplinary team has determined that the individual is a suitable living donor. (42 C.F.R. §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 C.F.R. §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)
 - D) There is verification of the compatibility of the donor and recipient blood type and other vital data immediately prior to organ recovery (i.e., right before the donation occurs). (42 CFR §482.92)

Note: This is *not* an exhaustive list of the Medicare CoPs 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*

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).

program must verify that these requirements are met prior to the transplant/donation occurring.

- 4) Monitor and evaluate the living donor services (i.e., pre-, during and post-donation) contract as part of the Quality Assessment and Performance Improvement (QAPI) program including the review of any adverse events. It is not expected that the recipient's transplant program would do a separate root cause analysis of the adverse event; however, there must be written communication between the two programs about that analysis adverse event and a description of the specific actions taken by the living donor program 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 format for these indicators.

- 5) Have a written process to ensure that the living donor transplant program that is under contract is addressing its own areas of Medicare non-compliance based on a CMS survey or the transplant program's knowledge of the minimum requirements of the CoPs.

Note: We would expect the process to be scaled to the type of arrangement. For an ongoing arrangement this would include receiving a copy of the survey findings and plan of correction for any deficiencies related to living donor care. In episodic arrangements (e.g., a one-time paired exchange between four transplant programs at different hospitals), it may be a more informal process such as a discussion among the transplant directors or administrators.

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.

C. 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 must include this contracted service as part of their review, as described in more detail below. In a multi-organ exchange (i.e., swap) among multiple transplant programs, surveyors will only review the specific program(s) that provided the living donor services for the specific recipient's case under review.

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

Table 1: Interim 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	<p>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?</p> <p>If the program provides living donor services under contract/arrangement, request the following items from the program:</p> <ol style="list-style-type: none"> 1) Written evidence of the contract or agreement with the living donor’s transplant program. This contract must outline the scope of the services provided and the process that will be used to facilitate the review and evaluation of these services; 2) A copy of the Medicare-approval letter for the transplant program providing living donor services under arrangement or contract; 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 - 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 4 - Observations of Care	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 5 - Sample Selection	In your living donor sample, include individuals who received some/all of their services at another transplant program.
Task 6 - 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.

	<p>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.</p>
<p>Task 7 - Review of Transplant Patient and Living Donor Medical Records</p>	<p>The transplant recipient’s program must have a copy of the living donor’s medical record prior to donation and must make the record available for a surveyor to review.</p> <p>Review the copy of the living donor’s medical record for compliance for the following areas:</p> <ul style="list-style-type: none"> • a complete medical evaluation; • a complete psychosocial evaluation; • determination of the living donor’s suitability for donation; • a full informed consent; • evidence of services provided by an Independent Living Donor Advocate, and • verification of ABO and other vital data immediately prior to the donor surgery. <p>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.</p> <p>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.</p>
<p>Task 8 - Staff Interviews</p>	<p>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.</p> <p>Include in your interview with staff questions about the monitoring and oversight activities of the quality of donor services provided under this contract/arrangement. For example, who reviews the living donor medical record to ensure that the minimum requirements are met? How is the contracted service monitored by the QAPI program?</p>
<p>Task 9 - Personnel Record Review</p>	<p>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</p>

	the contracted transplant program.
Task 10 - Administrative Review	<p><u>Hospital Contracts</u> Review the written agreement with the living donor transplant program. In most cases, this will be a contract/agreement between two hospitals, but it is also acceptable for there to be a contract/ agreement between two programs.</p> <p><u>Review of Quality Assessment and Performance Improvement Program (QAPI)</u> Review the recipient transplant program’s QAPI program to ensure: 1) that the program is monitoring living donor services (provided directly or under contract/agreement); and 2) that there is an analysis of any adverse event and specific actions taken to prevent repeat incidences.</p> <p>Please note that if the program is not providing <i>any</i> 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.</p> <p>Cite any deficiencies identified under the appropriate tags for the survey you are conducting at the recipient transplant program.</p>
Task 11 - Pre-exit	No change in surveyor activities.
Task 12 - 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 13 - 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.

D. Feedback on Policy Guidance

Given the complexity of the requirements and the changing nature of these types of arrangements, we are releasing this as interim guidance. We will review comments on the interim guidance to ensure that we are sufficiently addressing questions and concerns by the transplant community and CMS surveyors, and we plan to finalize the guidance in calendar year 2012. Please send your comments to Karen Tritz at Karen.Tritz@cms.hhs.gov.

Effective Date: The interim guidance is effective immediately. 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