



Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 13-10-Transplant

DATE: February 1, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Crosswalk Guide to the Organ Procurement and Transplant Network (OPTN) and the Centers for Medicare & Medicaid Services (CMS) Oversight of Organ Transplant Programs

Memorandum Summary

- **Development of Transplant Policy Crosswalk** - CMS, the Health Resources and Services Administration (HRSA) and the OPTN Contractor, the United Network for Organ Sharing (UNOS), have collaboratively developed a document that compares OPTN policy and CMS requirements and identifies areas of overlap. The crosswalk summarizes how CMS and OPTN conduct their oversight activities and what surveyors review during their onsite visits.
- **Ongoing Efforts to Address Survey Process and Overlap** - This Crosswalk is the first step in reviewing the two sets of oversight activities to identify potential policy changes and/or to improve the efficiencies in the survey process.
- **Background Information:** The material in this memorandum is largely informational in nature, designed to assist surveyors in better understanding OPTN requirements and the manner in which CMS and OPTN requirements mesh.

Transplant Oversight

Transplant programs are reviewed by both the Organ Procurement and Transplant Network (OPTN) and the Centers for Medicare & Medicaid Services (CMS) to determine compliance with OPTN Policies and Bylaws and the Medicare Conditions of Participation. OPTN and CMS review the transplant programs with separate and unique intent, criteria and responsibilities to the transplant community and the public.

Background

In 2011, The Advisory Committee on Transplantation (ACOT) established a working group to look at issues of policy alignment between CMS and OPTN. The potential alignment areas included: regulatory / policy changes, process changes and standardized documentation. In

November of 2011, CMS and HRSA formally requested feedback on the areas of overlap in the survey process and the review requirements from the transplant community. Representatives from UNOS, HRSA and CMS have been working together weekly since March 2012 to review and compare OPTN and CMS requirements and identify areas of overlap. The first deliverable from this review is the [Crosswalk Guide to the OPTN and CMS Reviews of Transplant Programs](#).

Purpose of the Crosswalk

The [Crosswalk Guide to the OPTN and CMS Reviews of Transplant Programs](#), found at http://www.optn.transplant.hrsa.gov/ContentDocuments/CMS-OPTN_Crosswalk.xls is an Excel file developed by the three organizations that compares CMS and OPTN requirements for transplant hospitals and how these requirements are routinely reviewed or monitored by CMS and OPTN. It does not include any requirements within the Medicare Hospital Conditions of Participation nor the CMS Organ Procurement Organization Conditions for Coverage. The [Crosswalk Guide to the OPTN and CMS Reviews of Transplant Programs](#) also identifies areas of overlap, minor discrepancies and the level of detail reviewed for each requirement. The crosswalk also briefly summarizes what reviewers/site surveyors from each organization will review during their visit. We realize that visits from multiple agencies require considerable preparation from the transplant center and we hope the use of this resource will make the process as efficient as possible. It is important for transplant hospitals surveyors to be familiar with and able to reference CMS and OPTN/UNOS requirements, terminology, and survey methods. We are therefore providing this crosswalk as a resource for transplant surveys. We hope this can also be used as a reference about similarities and differences with OPTN policy.

Specific Navigation of the Crosswalk

- The [Crosswalk Guide to the OPTN and CMS Reviews of Transplant Programs](#) is located on the OPTN Website at http://www.optn.transplant.hrsa.gov/content/policiesAndBylaws/evaluation_plan.asp.
- On the left hand side of the screen, locate the Policy Management tab.
- Click on the Policy Management tab and scroll down to the Evaluation Plan option.
- The Evaluation Plan screen contains links to both the OPTN Evaluation Plan as well as the [Crosswalk Guide to the OPTN and CMS Reviews of Transplant Programs](#).
- Click on the link entitled CMS/OPTN Crosswalk to open the document.

In the Crosswalk, the requirements are divided into four types: Administrative, Clinical, Human Resources and Quality Assessment and Performance Improvement (QAPI). Administrative requirements are those elements that relate to program operations, infrastructure and management. Clinical requirements are specifically related to patient care. Human Resources covers staffing requirements, and QAPI addresses CMS' requirements that each program have a structure program for quality improvement.

Each requirement is assigned a requirement number. This number may be referenced in the notes section if there is an overlap in some of the requirements. For example, the OPTN has one policy for living donor informed consent while CMS has several operational guidelines. Instead of listing the policy each time, we added a note to the notes column to point you back to the requirement type and number. You have the ability to filter your search by any or all of the requirement types. Below is a description of the content in each Column:

1. Column B is the requirement description.
2. Columns C and D tell you whether this requirement is reviewed as part of the deceased and/or living donor components of the site surveys. The next column shows you the applicable organ programs. You can filter by any or all of the organ programs.
3. Column F shows you which organization has oversight of this particular requirement.
4. The next column provides you with a link to the specific OPTN policy which addresses this requirement. If the OPTN does not currently monitor or have a policy addressing this requirement, this section will show N/A.
5. Column H provides you with the OPTN review method. This section provides guidance on how the OPTN will monitor compliance with this requirement.
6. Next you will find a link to the CMS regulation. If CMS does not have a corresponding policy, this section will show N/A.
7. Column J is the CMS review method, which includes their operational guidelines. Here you will find guidance on how CMS monitors compliance with this requirement.
8. Finally the Notes section contains any similarities or differences between OPTN and CMS on requirements. As mentioned before, there will also be references back to previous requirements in the document. Also, there may be links to supplemental information on OPTN/CMS review methods. Some of the requirements have additional notes, examples and details for you to review regarding monitoring methods.

Preliminary Analysis of the Crosswalk

In reviewing the findings of the Crosswalk and looking at opportunities for additional work between CMS, HRSA and the OPTN, there are three main categories of crosswalk requirements that have been identified that we would like to briefly summarize below.

1. ***Minor guidance differences:*** There are some policies that have overlap but also minor differences in how they are reviewed. We are reviewing these internally for CMS interpretive guideline changes. Examples of some of these areas are, “A085: Removal of a candidate from the wait list within one day/24 hours. Each organ has a similar policy with the same requirement as noted in the crosswalk. The differences in the two policies include CMS with 24 hours and OPTN with one day as their definitions. To aid in the compliance for programs CMS is reviewing the option of adjusting their requirement to accept the one day definition as required by the OPTN.
2. ***Similar review/survey requirements:*** There are also a few areas that both CMS and OPTN have very similar requirements and survey or review these requirements in a similar manner. For example, the reviews of living kidney donor policies and procedures for receiving a medical and psychosocial evaluation are similar. The OPTN site surveyors review policies and procedures to verify that they meet OPTN requirements and interview staff and review medical records for documentation of understanding and completion of these requirements. CMS surveyors use similar surveying methods (review of policy, medical records and interviews) to verify that prior to donation, an individual receives a medical and psychosocial evaluation and that evaluation is completely independent of the recipient evaluation.

3. ***Separate review/survey requirements:*** There are also areas that our respective organizations require that the other does not require. For CMS this main requirement is Quality Assurance and Program Improvement requirements (see Q099-Q104 in the Crosswalk). The OPTN has many requirements that maintain the integrity of the national waiting such as updating appropriate labs and vessel storage.

The crosswalk will be a useful tool for CMS, HRSA and UNOS to review the requirements in all three of these broad categories to determine the need for long term action and next steps. Though it is largely informational in nature, we also expect that it will assist transplant surveyors better understand OPTN requirements, the manner in which CMS and OPTN requirements mesh, and any differences that may exist.

Effective Date: Immediately. This tool should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management