OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

700 North 4th Street, Richmond, VA 23219
tel: 804-782-4800
fax: 804-782-4816
optn.transplant.hrsa.gov

July 23, 2019

James Cowher
Acting Director
Division of Continuing Care Providers
Quality and Safety Oversight Group
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, MD 21244-1850

RE: QSO-19-11-Transplant. Medicare Program: Transplant Program Survey Activity Transition

Dear Mr. Cowher,

The Organ Procurement and Transplantation Network (OPTN) Executive Committee offers the following comments in response to CMS's Memorandum QSO-19-11-Transplant, dated March 29, 2019. These comments address the published guidance on activities and expectations of State Survey Agencies (SAs) as the entity conducting all survey activity for approval and re-approval of Medicare transplant programs since January 1, 2019.

Background

The OPTN is administered under contract with the Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS), pursuant to the National Organ Transplant Act of 1984, as amended (NOTA). United Network for Organ Sharing (UNOS), a Virginia not-for-profit corporation, is the current OPTN contractor. Guided by the OPTN Final Rule § 42 C.F.R. Part 121, a major OPTN objective is the continued improvement of national policies to maximize the benefit of transplantation to those with end-stage organ failure.

The OPTN provides input on federal issues with potential impact on the fields of organ procurement and transplantation, such as this Memorandum QSO-19-11-Transplant related to CMS transplant program survey activity.

OPTN Comments

While the OPTN supports CMS providing written guidance to assist with this transition, there are concerns with Sections X-081, X-121, and X-122 related to the Independent Living Donor Advocate (ILDA) or the Independent Living Donor Advocate Team (ILDAT). As written, these sections conflict with current OPTN policies and transplant program staffing and practice related to the ILDA or ILDAT.

700 North 4th Street, Richmond, VA 23219
tel: 804-782-4800
fax: 804-782-4816
optn.transplant.hrsa.gov

Section X-081

Guideline §482.94: Conditions of Participation: Patient and Living Donor Management

Relevant excerpt: "*...Some transplant programs perform living donor services under arrangement with other hospitals. In these cases, the transplant program retains all responsibility for compliance with management of the living donor. The Transplant program must communicate the donor management activities that are required as a part of the living donor organ recovery to the hospital under the arrangement and ensure that the activities are completed appropriately.*"

> OPTN **Comments:** Current *OPTN Policy 14.6: Placement of Living Donor Organs* requires the transplant surgery using a living donor organ to be performed at an OPTN member transplant program. As such, any hospital performing living donor organ recovery is already accountable for the donor management activities under existing OPTN policy. It is unrealistic to expect that the recipient's transplant program, especially in situations such as a kidney paired donor exchange, can manage donor care activities at another hospital in a real and responsible manner. If this language must remain, the OPTN requests a modification to indicate that this does *not* apply to kidney paired donor exchange situations where the donor organ is recovered in another transplant program.

Section X-121

§482.98(d) *Standard: Independent Living Donor Advocate or Living Donor Advocate Team. The transplant center that performs living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors.*

Guideline §482.98 (d) *Every potential living donor must be assigned to and have an interview with an Independent Living Donor Advocate (ILDA) or an Independent Living Donor Advocate Team (ILDAT) prior to the initiation of the evaluation and continuing to and through the discharge phase.*

> OPTN **Comments:** *OPTN Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements*, requires that all potential donors are assigned an ILDA or ILDA Team; informed of the ILDA role and requirement; and provided information on how to contact the ILDA.
>
> The OPTN does not think it is advisable for ILDAs to interview patients prior to evaluation, and requests removal of this guideline because it is not reflective of policy or transplant hospital practice. Moreover, the content and purpose of the "interview" is not clearly defined, nor is "initiation of evaluation." For example, "initiation of evaluation" could be interpreted to mean that a hospital could not take simple and efficient initial screening steps such as a blood test or have a single conversation with a living donor coordinator prior to the interview.
>
> Second, ILDAs are not substitutes for the social workers, physicians or transplant coordinators who educate potential donors. They are advocates for the rights of the living donor. The living donor coordinator, social worker, physician and others educate and coordinate the potential donor through the process toward consent. The ILDA is required to ensure that the potential

700 North 4th Street, Richmond, VA 23219
tel: 804-782-4800
fax: 804-782-4816
optn.transplant.hrsa.gov

donor receives all required information, to advocate for their rights throughout the process, and to protect their interests. Under these requirements, if the interview is conducted prior to the transplant team's involvement, the ILDA will not be able to properly assess if the potential donor has received and understands the required education nor address any of the patient's questions.

Third, this guideline poses unnecessary costs and burden on transplant programs by requiring additional ILDA staff to ensure that every potential living donor receives an interview with an ILDA prior to starting the evaluation. Many potential donors are removed from consideration after initial screening. Requiring an ILDA to interview potential donors before any initial screening and so early in the process places undue time and resources to the living donor process, including additional federal government expense in the form of cost report reimbursement. Requiring ILDAs to interview donors prior to initiating, rather than during, the evaluation is excessive and not reflective of the ILDA role.

Finally, we encourage CMS to consider the practical implications of guidelines on potential living donors. Specifically, OPTN policy seeks to fully protect potential living donors' distinct interests in the transplant system. The policies give transplant hospitals the ability to implement them in a way that is most efficient and responsive to potential donors. We encourage CMS guidelines to be cognizant of the need for some basic administrative judgment as they strictly execute the policies so that hospitals do not inadvertently discourage or frustrate people who step forward to learn more about donating an organ. Conducting this interview prior to detailed education from the clinical team may be confusing to many donor candidates.

Section X-122

§482.98(d)(1) *The living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis.*

Guideline §482.98(d)(1): *Because of the conflict of interest which would be created for an advocate to perform any transplant activities, even on an infrequent basis, the ILDA or ILDAT must not be associated with the transplant program in any capacity even on a temporary or intermittent basis.*

OPTN Comments: The spirit of this regulation is to ensure that the donor has someone to advocate with their best interests in mind to guide them through the transplant process. The OPTN believes that the advocate should be knowledgeable about transplant and have the mechanisms to stop the evaluation process or the donation if there are significant concerns.

In order to be informed and involved in living donation, the ILDA will naturally be involved in transplant activities. Potential living donors may find value in a professional ILDA who is involved in and therefore knowledgeable about the specific transplant program.

Read strictly, the guideline requiring no association with the program in any capacity could be interpreted to require the ILDA to be wholly external to the hospital, which would raise a number of practical and administrative issues and could cast doubt over an ILDA's expertise in connection with the transplant program.

700 North 4th Street, Richmond, VA 23219
tel: 804-782-4800
fax: 804-782-4816
optn.transplant.hrsa.gov

Transplant programs have developed different ways of ensuring the independence and strength of the ILDA role. Smaller transplant programs have been resourceful in ensuring a knowledgeable and experienced team member in a non-conflicting role serves as the ILDA. Larger transplant programs often have a full time ILDA embedded in the transplant team in order to be effective and accessible.

The OPTN believes that the best way to ensure the independence and strength of the role is by reviewing the job description for the ILDA, interviewing the ILDA, and reviewing the ILDA notes in donor charts, but not by requiring that the ILDA be removed from the operations of the program or to proscribe any association with it.

The OPTN agrees that the ILDA should not be primarily involved in recipient activities but suggests that the focus of this guideline be altered to state, *"The Living Donor Advocate and Living Donor Advocate Team must keep the rights of the living donor as their sole focus. They should have the ability to stop an evaluation or a donation if significant concerns arise."*

We appreciate the opportunity to comment on these guidelines, aimed to assist in the transition of transplant program survey activity back to State Survey Agencies. Our goal is to increase alignment between CMS regulations and OPTN policy.

We urge CMS to align these guidelines with OPTN policies as outlined. In addition, through references to OPTN policy, the guidelines could be constructed in a manner that would continue alignment even if OPTN policies change. These actions would reduce unnecessary inefficiencies while helping transplant resources remain focused on efforts to protect living donors and successfully transplant candidates on the waiting list.

If you have any questions regarding our comments, or if we can provide additional information that will be useful as you consider the matter further, please contact Chelsea Haynes, Manager of Board Relations at chelsea.haynes@unos.org.

Sincerely,

Maryl Johnson, MD
OPTN President