

**OPTN Patient Affairs Committee
Meeting Summary
February 15, 2022
Conference Call**

**Garrett Erdle, M.B.A, Chair
Molly McCarthy, Vice-Chair**

Introduction

The Patient Affairs Committee (the Committee) met via Citrix GoToMeeting teleconference on 02/15/2022 to discuss the following agenda items:

1. COVID-19 and the Organ Procurement and Transplantation Network (OPTN) Actions – Presentation and Discussion
2. Centers for Medicare and Medicaid Services (CMS) Request for Information (RFI)

The following is a summary of the Committee’s discussions.

1. COVID-19 and the OPTN Actions – Presentation and Discussion

Staff presented a summary of actions taken by the OPTN) in response to the COVID-19 emergency.

Summary of discussion:

Staff presented a brief summary of the following actions:

- *Updates to Candidate Data During the 2020 COVID-19 Emergency*
- COVID-19 Emergency Policy Package
 - *Modifications to Wait Time Initiation for Non-Dialysis Kidney Candidates*
 - *Incorporation of COVID-19 Infectious Disease Testing on DonorNet*
 - *Relax Data Submission Requirements*
- *Require Lower Respiratory SARS-CoV-2 Testing for Lung Donors*
- *Reinstatement of Updates to Candidate Data During the 2022 COVID-19 Emergency*

The Vice Chair inquired how *Updates to Candidate Data During the 2020 COVID-19 Emergency* changed program behavior, and how programs could enter forms into amnesty status. Staff responded that the initial policy change allowed programs to delay the timing of required laboratory testing and still maintain candidate status without being penalized. Forms would automatically enter amnesty status if they were not submitted by the thirty day timeline specified in OPTN policy.

A member inquired as to what patient input was taken into account during the development of these policies. Staff replied that the policies were informed by the experiences of transplant programs interacting with their patients, and were submitted for retrospective public comment to ascertain how they were received. Additionally, programs were given a free response field within UNetSM to report issues experienced with COVID-19, and some of these issues were submitted on behalf of patients. Finally, the member questions and patient services line also received inquiries about best practices for programs and patients.

A member voiced support for more information from transplant programs specifically targeted towards patients. From the member’s experience, they had not received enough information surrounding the

COVID-19 vaccine, monoclonal antibody treatment, and the risk of infection in immunocompromised individuals. They were supportive of the actions taken to ensure the safety of transplant patients before, during, and immediately after transplant, but wished for more actions to have been taken on behalf of the patient and donor community.

Staff identified some of the resources available on the COVID-19 section of the OPTN website, but acknowledged these may not be as specific as desired on a case-by-case basis.

A member added, with the support of a number of members of the Committee, that it would be hard for the OPTN to develop specific guidelines for programs as the COVID-19 pandemic affects programs differently. Therefore, it would be difficult to develop anything other than a general summary of the existing information.

Another member contributed that they had experienced frustration trying to get specific information from their programs surrounding COVID-19 antibodies and being immunocompromised, and had received different answers from two different programs. A second member supported this opinion, and stated that there should be uniform guidance on general questions where the answer is known.

A third member responded to these opinions, anecdotally mentioning that the director of transplantation at their program did not know that a fourth shot had been approved, and mentioning that the pandemic has presented a challenge at all levels of the transplant network. They advocated for the patients who are involved in transplant societies being a source of guidance for the rest of the patients.

A representative from the Health Resources and Services Administration (HRSA) voiced an opinion, stating it was not representative of HRSA, that they felt like both federal and private organizations could have done more to provide clear communications to patients. The representative added that there were complications for any organization with the COVID-19 pandemic, but that does not excuse the lack of guidance for previously transplanted patients. Furthermore, they added that the OPTN and UNOS do not have a significant amount of leeway to directly interact with patients or provide clinical advice, but that the government has historically provided information in times when national emergencies impacted a large number of individuals (e.g. hurricanes, natural disasters, etc.). The HRSA representative concluded by offering the consideration that, similar to how other Committee members have said, amidst the chaos surrounding the pandemic, immunocompromised transplant recipients could have been provided more information.

It was suggested that, similar to how the OPTN passed policy-level guidance for lower respiratory testing for lung donors, that programs should be encouraged to explain this change in reporting requirements to patients. This, a member contributed, would help fill “the complete void of information” surrounding what was being done to protect transplant recipients. The Chair added that this should be seen as a learning opportunity, as it exposed a breakdown within the normal communication channels when emergent information was needed.

2. Centers for Medicare and Medicaid Services (CMS) Request for Information (RFI)

The Committee received an update on the CMS RFI and the OPTN’s response.

Summary of discussion:

The OPTN produced a comment which can be found [with other submitted comments](#). Public comment for the RFI closed on February 1, 2022.

Staff also detailed the organization of the Department of Health and Human Services, and what CMS’s relation to HRSA is, and by extension, the Division of Transplantation.

Due to time constraints, this item was not discussed.

Upcoming Meetings

- March 10, 2022
- March 11, 2022

Attendance

- **Committee Members**
 - Molly McCarthy
 - Darnell Waun
 - Diego Acero
 - Betsey Brada
 - Julie Ice
 - Sarah Koochmaraie
 - Kenny Laferriere
 - Earl Lovell
 - Anita Patel
 - Sejal Patel
 - Kristin Ramsay
 - James Sharrock
 - Julie Spear
 - Eric Tanis
 - Justin Wilkerson
 - Christopher Yanakos
- **HRSA Representatives**
 - James Bowman
 - Raelene Skerda
- **SRTR Staff**
 - Katie Audette
- **UNOS Staff**
 - Isaac Hager
 - Lindsay Larkin
 - Eric Messick
 - Anne Paschke
 - Tina Rhoades
 - Susan Tlusty
 - Kim Uccellini
 - Sara Rose Wells
- **Other Attendees**
 - Wagner Rodrigues
 - Calvin Henry