

OPTN/UNOS Operations and Safety Committee
Public Comment Review Meeting
LiveMeeting teleconference
December 12, 2012
1:00 pm – 2:00 pm (ET)

Public comment proposal review:

The Committee reviewed three proposals out for public comment. A quorum was not present for each of the proposals presented during this meeting. The Committee did however provide feedback on each of the presented proposals as noted below:

1. Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions (Organ Procurement Organization (OPO) Committee)
Committee feedback provided:
 - The Committee discussed regarding the proposed change in the definition of I&E for OPTN data reporting requirements but that CMS requirements for data reporting will be different. Was there discussion among the OPO committee members about how this difference in data submission and regulation enforcement would be handled?
 - Transplant center members raised concerns that this proposal changes the definition of an eligible donor. This change may significantly increase in the number of organ offers made by OPOs that try to exhaust the list on donors that would previously have not been a potential donor.
 - Because the change in the definition of MSOF, OPOs may approach donors that they would not have previously approached and be inclined to make offers in order to demonstrate that they have exhausted the match run. There is concern that this could negatively affect the number of organs per eligible donor.

2. Proposal to Require Reporting of Every Islet Infusion to the OPTN Contractor Within 24 Hours of the Infusion (Pancreas Transplantation Committee)
Committee feedback provided:
 - How will patients be tracked after 3 infusions and removal from the waiting list? This proposal may cause some confusion for those that have following previous requirements for islet listings. Please provide guidance on how a patient's waiting time can be re-instated in the case of a removal error.
 - This proposal is a good idea in order to track islet infusion recipients and will help the OPO to obtain recipient information in case a potential disease transmission is identified and notifications need to take place.

3. Proposal to Substantially Revise the National Kidney Allocation System (Kidney Transplantation Committee)
Committee feedback provided:
 - This proposal represents many years of work on the part of the Kidney Committee and represents the best interest of the patient that is waiting.
 - This is the best proposal that has come forward among the different iterations of the past decade. Dialysis start date is overall a good thing but maybe there should be a maximum of years given (such as 4 years) for patients that did not come forward early. Understanding the justice aspect of the issue and lack of referrals, 4 years would take care of most referrals that are not made early in the disease process. An approach like this may make it easier for patients that wait for a kidney, then see someone jump

ahead of them only because a referral was not made early. For example: A patient that had been on dialysis for 12 years but never completed the transplant evaluation. Instead of that patient going straight to the top of the list, that patient would get 4 years (which is what is given to previous living donors). More waiting time could be accrued.

- There is concern that ECD kidneys that are heavily utilized by transplant centers (such as Atlanta) may be mostly diverted to other centers that do not have the same OPO and geographic patient base. It would be nice to see ECDs shared locally since the concern is that these offers will greatly decrease in certain areas.
- Many transplant centers struggle to maintain their kidney waiting lists. A high priority for this proposal, once approved, should be guidance and training for kidney centers on how to manage their waiting lists better.

Meeting Adjourned.