Improving Human Life by Advancing the Field of Transplantation

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MEMORANDUM

To: Dr. Kenneth Andreoni, UNOS President
Mr. Brian Shepherd, UNOS Interim CEO

From: Ms. Libby McDannell, Executive Director
American Society of Transplantation (AST)

RE: AST Comments on OPTN Policy Rewrite

Date: September 9, 2013

On behalf of the American Society of Transplantation Board of Directors, I am attaching the Society's comments on the OPTN plain language rewrite.

Please let me know if the AST can be of further assistance and thank you for the opportunity to comment on this rewrite.

Cc: AST Board of Directors
Dr. Maryl Johnson, AST's UNOS Board Representative

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WORLD TRANSPLANT CONGRESS 2014

July 26–31, 2014
San Francisco, CA

AST Comments
OPTN Policies Plain Language Rewrite
September 9, 2013

Policy 1: Administrative Rules and Definitions
We believe that this policy is well organized, clear and is just a plain language rewrite. We did not see any substantive changes to current policy. On page 12: definition of Transplant Date, it was clear under current policy that the transplant date is the beginning of anastomosis. However, it was not clear that the transplant date for each organ is determined by the beginning of anastomosis of the first transplanted organ. This information could not be located in the current policy.

Policy 2: Deceased Donor Organ Procurement
In general we think the policy is straight forward and easy to read. A few comments:

2.1: We request clarification on the second sentence. If an OPO determines the patient not to be a suitable donor we were not aware that any OPO would then offer the potential donor to another OPO. Is this what the policy means? It is certainly not the practice.

Sections 2.8.A to 2.8.E. It would be better if these sections were formatted in a uniform fashion, ie present the history, laboratory information and anatomic data in the same order for all of the organs.

2.9.B. We would change "Swan Ganz instrumentation" to "CVP, pulmonary artery pressure, pulmonary capillary wedge pressure, and cardiac output defined using a pulmonary artery catheter"

Policy 3: Candidate Registrations, Modifications, and Removals

We believe that this policy is well organized and do not see substantive changes. Some aspects of the policy are converted into a table format which is more user friendly.

Policy 4: Histocompatibility

Section	Observation
4.1	The first sentence is trying to combine criteria for membership (serving at least one program) with the requirement for written contracts with each program. The first sentence should read "Histocompatibility Laboratories must have written contracts with **each** transplant program **they serve**."
Table 4-2	Title should read: "Assays to Identify Antibody to HLA: Screening, Specificity or Crossmatching." Otherwise it loses original intent.

	Also, the last entry in this table should read “autologous” (not autologoum) cells.
4.2.D.1	Lost meaning. “**Use templates** with sufficient specificity……
4.3	The first paragraph needs a rewrite. It appears they are trying to identify how the tables are used in the match run algorithm but it comes off as instructions to the labs? This language was not in the original policies – the committee needs to step in to rescue this interpretation with appropriate language. Last part of paragraph 2 also needs help.
4.4	The rewrite of the instructions has lost the original meaning. In the original it is the lab that needs to correct its typing that has the onus to report its corrected data to the OPTN contractor. This rewrite has the lab with the correct typing reporting a change it did not have to make or reporting for the lab that made the mistake??
4.5C 1	Lost meaning. The intent is to require the lab to use panels that reflect the phenotypic distribution of their donor/candidate population
4.6B	It would appear that there would be an easier way to state this as all donors and candidates must be prospectively typed for HLA-A, B, Bw4,Bw6, DR, DR51, DR52, DR53, C and DQB. Wouldn’t it simplify things just to have one list rather than three separate statements? Another option would be to make this a table.
4.10.A	“Stored” should be “Store”
4.10.B	Number 3 should standalone as an individual sentence not as part of the list – it refers to all electrophoresis not only the “size is a critical factor” assays.
4.10.D.i 8	This refers to verifying the accuracy of the thermocycler temperatures not the storage of samples. It should be merged with 7.
4.10.G	Would benefit from one of the “must do all of the following:” lists for clarity and consistency
4.10.J	The statement requiring validation was left out – very important.
4.11.A	Merge 8 and 9
4.11.	Confusion created. There should be two sections here: crossmatching and phenotyping with subsections under each. For phenotyping: 4.11.E, F,G, H. For crossmatching 4.11.B,C,D. 4.11A applies to both
4.14	Should refer to section 4.10 not Section K.

Policy 5: Organ Offers, Acceptance, and Verification
We did not review this particular policy.

Policy 6: Allocation of Hearts and Heart-Lungs
This section of the rewrite is much improved from the original one presented last summer, particularly in more specifically outlining whether hospitalization is required for the various Status 1A categories.

A few minor comments:

1. On page 73 in the first entry in Table 6-3 under “Qualification” the statement “or an affiliated Veteran’s Administration (VA) hospital” should be added so that this entry reads “Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, or an affiliated Veteran’s Administration (VA) hospital”.

2. On pages 77-78, in the end of Table 6-6 Allocation of Hearts from Deceased Donors At Least 18 Years Old, entries 37-61 refer to allocation to peds patients with incompatible blood types and In utero candidates. These entries should be removed as this sequence is not included in current policy and an adult donor heart would just never be appropriate for a pediatric recipient under age 2 (which is what is required for incompatible blood type allocation) or an in utero candidate. We had made this comment on the previous version of the rewrite and the entries weren't removed, so wonder if the programming is done this way or something so they feel it needs to be included even though not mentioned in current policy and not a realistic possibility. This isn't a clinical issue and the entire In Utero category is likely to go away soon (as this was in the revised Pediatric Heart Allocation policy out for Public Comment last spring) but since this isn't included in current policy it would appear that any reference to allocation of adult hearts to pediatric candidates with incompatible blood type or In utero candidates should be removed.
3. On page 82, Classification 71, "or Zone A" should be removed to reflect what is in the current policy.

Policy 7: Allocation of Intestines

We have only one comment on this policy rewrite:

7.1.A 'A candidate may be assigned status 1 if the candidate has any of the following conditions:
. liver function abnormalities'

This statement is very vague and should be more specifically defined – what exactly constitutes 'liver function abnormalities'?

Policy 8: Allocation of Kidneys

Old language is almost verbatim in new policy. A few comments:
(N.B. This is repetitious of what is stated below for Table 8.4 and the order fits better when included below).

Section 8.7.A
Small typo in the sentence "Kidneys shared as zero mismatches or for candidates with CPRA greater than or equal to 99% in classifications 1 through 10 in allocation sequences in Table 8-5 through 8.8 above, " the 8.8 should be 8-8 to be consistent.

8.5.B
The KDRI score is rounded to the nearest integer – should this be "The KDPI score is rounded to the nearest integer"?

Table 8.4
Heading on the left column reads: "Hearts from Donors with…" – should be "Kidneys from Donors…"

Table 8.4
"Blood type non-A1 and non-A1B" category – should this state "Blood type A or AB donors that are subtyped as non-A1 or non-A1B" - just to be clear – "non-A1" could mean blood type O or B, right?

Table 8.5, categories 14 and 15 and several others

Does a candidate have to be less than 18 years at the time of the match run, or just listed prior to age 18 to get pediatric priority (in category 41 the language changes to "candidate listed prior to 18 years…")

Table 8.4, categories 14 and 15
Does it make sense to say "but no greater than 100%" – can it be greater than 100%? That may be the least "wordy" way to convey that grouping (80-100%) but it reads a bit oddly

Table 8.4, category 13
Does this group need cPRA parameters too?

Table 8.8, Rows 11 and 12 are redundant (same thing)

Policy 9: Allocation of Livers and Liver-Intestines
Specific comments on this policy are outlined below:

Under 9.1, why is "any" italicized in "Liver candidates less than 18 years old may be assigned any of the following:" for children but not the similar adult phrase above?

Under 9.1.A.1.b,c: why does there need to be both b. and c.? B seems to refer to a full liver, while c seems to refer to a segment of a liver, but both have exactly the same definitions below them (except AST greater than or equal to 3,000 is not indicated in c.) . If this is even an important distinction, why not just say "Primary non-function of a transplanted liver or liver segment within 7 days of transplant, evidenced by at least one…" The rewrite in this case has added a bullet point, and we don't think this makes the picture more clear.

Under 9.1.B.1: why is diagnosis of HAT done without a bullet point? It seems like it should have its own bullet just like in the adult section above.

Under 9.1.F: the sentence "Candidates less than 18 years old will receive a 23 point increase in their calculated MELD or PELD score instead of the 10 percentage point increase," is really unclear (we understand that this same wording was taken from the original policy, but it is unclear there, too). What is confusing is the "23 point increase". Does this mean a 23 percentage point increase, or to a raw number (eg MELD = 23). We think this could be easily clarified.

Under 9.3.D: Portopulmonary Syndrome: this language was unclear in the original policy, and its unclear now. The most basic thing not said is that the patient must have the diagnosis of Portopulmonary Syndrome by documentation of MPAP $\geq$ 35 mm Hg—this should be simply and explicitly stated. And, the proper name is "Portopulmonary Hypertension" (not Syndrome) and given the troubles many people have distinguishing between this and Hepatopulmonary Syndrome, it would seem better to do everything possible to distinguish these terms, give the entity its proper name of Portopulmonary Hypertension.

Under 9.6.H: similar to above, "Candidates less than 18 years old will receive a 23-point increase in their calculated MELD/PELD score instead of the 10% increase." Is this a 23-point MELD point increase or an increase equivalent to a 23% risk of 3-month mortality?

Tables 9-6, Classifications 41-52; 9-7, Classifications 34-45; 9-8, Classifications 33-44; 9-9, Classifications 45-56; 9-10, Classifications 37-48: It is unclear both in the original and re-written

policies what use of donor livers for "other methods of hepatic support" actually means, and some clarifying statement would be helpful.

Table 9.7, line for Classification 13. The word "at" is missing in the right column. It appears that this should read "MELD less than 15 and at least 18 years old".

Table 9.9 Classification 11, shouldn't this have MELD/PELD of 36 at the end of the line?

Policy 10: Allocation of Lungs
Please consider the following comments on this policy section rewrite:

Table 10-2 should go prior to the equation for the LAS

Table 10-2:
Bi coefficient is grouped for PTAUC measure but it defines waiting list coef
K and Stx is not defined for the PTAUC equation

Table 10-3: It may be helpful to put in more simple terms what the coefficient means for non-statistical people (does a higher age mean that you have a higher wait-list urgency?) This is really important for the general transplant community that is not statistically savvy.

Table 10-3: consider adding a return and space before 0.0462410402627318*PA in #26

10.1.F.ii:

Page 147: "I" is capitalized inappropriately in the sentence "There are two Increase in PCO2 calculations.

In general, this page is pretty confusing. From table 10-2 and 10-3 we cannot tell how the Increase in CO2 calculation B coef weight is different from the Threshold change in Maintenance. It doesn't seem as it is. If it is, then this needs to be clarified.

The section on the Threshold Change in Maintenance is really confusing with the current PCO2 and the lowest PCO2. It appears that there are perhaps two ways that CO2 level factor into the LAS. One compares the highest PCO2 to the lowest in a 6month window. Another compares the current PCO2 to the lowest PCO2 (whenever)—however this wouldn't be considered if there wasn't a rapid decline (within 6 months). As mentioned above, we could not tell if either calculation is weighed differently in the LAS.

To me it sounds like you are trying to say the following:
For those patients that have had qualified for a 15% increase in CO2 within 6 months, the current PCO2 value will be compared to the lowest PCO2 used to define a significant increase in CO2. The lowest PCO2 can be expired, however, the Current pCO2 has to be within 6 months .

We have similar comments to the bili and the Cr sections.

10.1.F.iii, in the paragraph under Increase0in-Bilirubin Calculation, line 4, "Contractor" should appear after OPTN rather than later in the line.

On page 150 in the first two lines under 10.2.A , sensitized candidates is mentioned twice which is redundant. One should be deleted.

On page 152 in the second line of the first paragraph under 10.3 Waiting Time "and" is not needed and should be removed.

On Page 155, Table 10-6, Classifications 25 and 26 should read "12 to less than 18 years old…"

On page 156, in Table 10-6, it appears that Classification 35 should read "Priority 1, blood type identical to the donor".

Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets
Overall, the policy reads much more cleanly but still accurately reflects old language. We have a few questions and suggestions below for consideration:

11.4.A
What requirements do <18 yr olds need to meet to be registered and accrue waiting time? Would be good to refer to appropriate policy(s) for this information within this policy.

11.4.C
This is unclear – what does a registration equal? Is it the same as an infusion?

11.5.A Kidney-Pancreas Allocation Order
Is there a reason that Tables 11-4 and 11-5 aren't physically associated with the referring text (i.e. 11.5.A and B)? It seems more difficult to navigate and determine the priority of the content in the Table in relation to other elements of the Classifications and Rankings, including Table 11-3.

Table 11-3
What takes precedence? O to O or O to A/B/AB with 0 Ag mismatch and cPRA >80%? In Current policy 3.8.3.2, there is clarity as to what situation is priority. We would advise noting this somehow within the Table.

Current Policy 3.8.6 Removal of Pancreas Transplant Candidates from Waiting Lists.
We did not find a matching discussion in the rewritten policy to reflect the responsibility of the Organ Center to remove the patient from the waiting list upon transplantation or death.

Policy 13: Kidney Paired Donation
Comments:

Page 175 – Policy 13.6.A > 3a – *Whether the candidate is a prior living donor.* Probably semantics but is this the right terminology? For example, if the candidate has NOT signed, then this person would not be a KPD candidate so.

Page 175 – Policy 13.6.A > 3a – *KPD status.* What is meant by "KPD status"? Please clarify.

Page 175 – Policy 13.6.A > 3b - *Whether the candidate would be willing to travel, and, if so, the transplant hospitals to which a candidate would be willing to travel*. Seems ambiguous. If a candidate is willing to travel ANYWHERE, then would they have to list every single transplant center?

Page 175 – Policy 13.6.A > 3b – *Maximum acceptable donor BMI*. What donor BMI is a critical factor to specify?

Policy 14: Living Donation
Overall the proposed policy re-write is effective. Not much of the original language has been changed reflecting the fact that this policy has been recently written. The intent of the original policy is not changed by the re-write. The removal of elements of the policy such as data reporting and vessels is appropriate and will lend itself to easier location of relevant policies on items. Reference to the location of the specific policy is helpful. Minor typo's are identified in the below table.

14.2 A	No change in intent of policy language. However, would suggest the emphasis on *all* is not necessary.
14.2B	No change in intent of policy language. However, would suggest the emphasis on *all* is not necessary.
14.3A.i	No change in intent of policy language. However, would suggest the emphasis on *all* is not necessary. # 6, language is awkward – would suggest the original policy language is clearer. Double)) after CKD. 6.a - ….permanent loss of kidney function at after donation. Delete 'after'.
Page 182, item 6.e	Doesn't read well and needs to be reworded (perhaps "when reaching" should be deleted?).
Page 182, item 7.a	Doesn't read well and needs to be reworded (perhaps "when reaching" should be deleted?).
Table 14.2	No change in intent of policy language. General Family History and Kidney-specific family history, Coronary Artery disease and cancer are repeated. Remove from Kidney-specific family history.
14.6	No change in intent of policy language. …..Additionally, each living donor program must develop and comply with a protocol to verify that the living donor's blood type and type was correctly entered on the…… Add blood type and sub-type.

Policy 15: Identification of Transmissible Diseases
Comments:

15.2 Second paragraph should remove wording "based on state law". No state law bans the use of transplanting HIV+ candidates.

15.3.A #3. Please clarify what they mean by "follow".

15.3.B #3 Entire sentence should be deleted. This is not in current policy and raises the question of what defines "routine post-transplant follow-up care." OPTN directing clinical care.

15.4.A First paragraph.
The language applies to live and deceased donors so the word "deceased" should be deleted.

15.4.B.
The first line should likely read "…OPO is…"

Under 15.4.B.#4, 3rd paragraph it is stated that:"If a host OPO learns new information regarding a deceased donor as part of its required living donor follow-up that indicates risk of potential transmission …". Is this intended to mean information regarding a" living" donor or "deceased" donor follow-up? As written it doesn't make sense.

The area that states the recovery hospital may also need to report the new information should clarify "if required" consult with local, state or federal regulation.

The first line should likely read "…OPO is…"

15.4.B, #3a., line 3, it appears that "to identify" is not needed.

Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage
We did not review this particular policy.

Policy 17: International Organ Transplantation
We believe that this policy is well organized but did find a few editorial and substantive changes:

17.2.A– 1. Submit a proposal to the adhoc…., then 2. Have approval of the agreement
17.2.A – 6. Replace "agent" by "his or her legal representative". This represents a substantive change
17.2.A.7. In the second line "met" is included twice and one of these should be removed.
17.2.B- 2. Add "in accordance with the allocation policy for that organ"
17.2.C-2. Replace "agent" by "his or her legal representative". This represents a substantive change

Policy 18: Data Submission Requirements
We believe that this policy is well organized and did not see substantive changes. Some aspects of the policy are converted into a table format which is more user friendly.

On page 207, 18.1, near the end of the first paragraph it appears that the word "be" should be added so that this reads "required for organ placement must be submitted…".

On page 209, 18.3, the first paragraph needs to be reviewed/revised – currently it is missing some punctuation or something as it just runs on and on.

Policy 19: Data Release
We believe that the policy is actually logically organized and relatively clear. Our one suggestion for clarity is to add the word “allocation” to 19.4 to read,” The OPTN Contractor may …..participating in **allocation** variances…..”

Also, on page 216, there appears to be an extraneous “at” in the end of the italicized entry near the top for “Transplanted kidney, liver, or pancreas status”.

Policy 20: Travel Expense and Reimbursement
We found substantive changes from current policy. Specifically:

20.1 omits "guests" found in original as well requesting members to have institution absorb costs
20.5c excludes reimbursement for alcohol

No other substantive changes found.

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