

OPTN/UNOS Policy Notice Retrospective Review of Clerical Changes to Policies

Policy/Bylaws Affected: Policies 5.4.C (Liver Offers), 8.5.A (Candidate

Classifications), and 18.1 (Data Submission

Requirements)

Public Comment: N/A

Effective Date: June 29, 2017

Problem Statement

In November 2014, the Board approved changes to the OPTN Bylaws that enable staff to make clerical, or non-substantive, changes to the Bylaws and Policies as they're identified, without prospective approval from the Executive Committee or Board of Directors as was previously required. This enables staff to make simple, clerical corrections such as:

- Capitalization or punctuation, as needed to maintain consistency with current policy
- Typographical, spelling, or grammatical errors
- Lettering and numbering of a rule or the subparts of a rule, according to style conventions in current policy
- Cross-references to rules or sections that are cited incorrectly because of subsequent repeal, amendment, or reorganization of the sections cited

The Executive Committee retrospectively reviewed and approved the clerical changes outlined below during their meeting on June 5, 2017.

Summary of Changes

The following clerical changes were made and will increase the accuracy and clarity of our Policies:

Clerical Change	Reason
Policy 5.4.C (Liver Offers): last paragraph, deleted the word "in" after the words "according to" in the cross reference	Redundant
Policy 8.5.A (Candidate Classifications): deleted words "KDRI-to-KDPI" that incorrectly modify the EPTS mapping table	There's no such thing as a KDRI-to-KDPI EPTS mapping table
Policy 18.1 (Data Submission Requirements): deleted word "liver" and replaced with "living" to correct the cross-reference	The correct cross reference is to <i>Policy 18.6:</i> Reporting of Living Donor Adverse Events, not Liver donor

What Members Need to Do

These clerical changes were implemented on June 29, 2017; members who keep printed copies of the OPTN Policies should reprint their copies for the latest updated version.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (example).

5.4.C Liver Offers

The host OPO must make the initial liver offer using only a match run that is less than eight hours old. The host OPO may only re-execute the match run for use in allocation sooner than eight hours if *one* of the following occurs:

- A previously accepted liver is later refused because there is a change in specific medical information related to the deceased liver donor
- The deceased donor liver has not been allocated within two hours of procurement
- New donor information is received that would screen any potential recipient from appearing
 on the match run due to donor acceptance criteria according to in Policy 5.5: Re-Execution of
 the Match Run Due to New Information

8.5.A Candidate Classifications

Each candidate on the kidney waiting list after turning 18 years old receives an Estimated Post Transplant Survival (EPTS) score. A candidate's EPTS score represents the percentage of kidney candidates in the nation with a longer expected post-transplant survival time. EPTS is based on *all* of the following:

- 1. Candidate time on dialysis
- 2. Whether or not the candidate has a current diagnosis of diabetes
- 3. Whether or not the candidate has had any prior solid organ transplant
- 4. Candidate age

If a kidney recipient returns to the kidney waiting list, only time on dialysis after the most recent kidney transplant applies for number 1 above, candidate time on dialysis, as defined in *Policy 8.4: Waiting Time*.

Each candidate's EPTS score is calculated when the candidate is registered on the waiting list. The OPTN Contractor will update EPTS scores as follows:

- All candidate EPTS scores are updated once each day
- A candidate's EPTS score will be updated anytime the transplant hospital reports changes to any EPTS factor for a candidate

A candidate's raw EPTS score is equal to:

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0.047 * MAX(Age - 25, 0) +
-0.015 * Diabetes * MAX(Age - 25, 0) +
0.398 * Prior Solid Organ Transplant +
-0.237 * Diabetes * Prior Solid Organ Transplant +
0.315 * log (Years on Dialysis + 1) +
-0.099 * Diabetes * log(Years on Dialysis + 1) +
0.130 * (Years on Dialysis = 0) +
-0.348 * Diabetes * (Years on Dialysis = 0) +
1.262 * Diabetes
```

The EPTS calculation uses all the following as binary indicators:

- 1. Diabetes,
- 2. Prior solid organ transplant
- 3. Years on dialysis=0

If a binary indicator is true, then it is replaced by a value of 1.0 in the calculation; otherwise, it is replaced by 0. Fractional calendar years are used for candidate's age and years on dialysis.

The OPTN Contractor's KDRI-to-KDPI EPTS mapping table is used to convert a candidate's raw EPTS score into an EPTS score. All EPTS scores are rounded to the nearest integer.

The reference population used to determine the top 20% EPTS threshold is reviewed annually by the Kidney Transplantation Committee and updated by the OPTN Contractor on or before June 1 of each calendar year.

18.1 Data Submission Requirements

Members must report accurate data to the OPTN Contractor according to *Table 18-1* below. Members are responsible for providing documentation upon request to verify the accuracy of all data that is submitted to the OPTN through the use of standardized forms.

Table 18-1: Data Submission Requirements

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For:
Histocompatibility Laboratory	Donor histocompatibility (DHS)	30 days after the OPO submits the deceased donor registration	Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory
Histocompatibility Laboratory	Recipient histocompatibility (RHS)	 Either of the following: 30 days after the transplant hospital removes the candidate from the waiting list because of transplant 30 days after the transplant hospital submits the recipient feedback 	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory
OPOs, all	Death notification records (DNR)	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	All imminent neurological deaths and eligible deaths in its DSA
OPOs, all	Monthly Donation Data Report: Reported Deaths	30 days after the end of the month in which a donor hospital reports a death to the OPO	All deaths reported by a hospital to the OPO

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For:
Allocating OPO	Potential transplant recipient (PTR)	30 days after the match run date by the OPO or the OPTN Contractor	Each deceased donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient
Allocating OPO	VCA Candidate List	30 days after the procurement date	Each deceased donor VCA organ that is offered to a potential VCA recipient
Host OPO	Donor organ disposition (feedback)	5 business days after the procurement date	Individuals, except living donors, from whom at least one organ is recovered
Host OPO	Deceased donor registration (DDR)	30 days after the donor organ disposition (feedback) form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	Living donor feedback	The time prior to donation surgery	Each potential living donor organ recovered at the hospital This does not apply to VCA donor organs
Recovery Hospitals	Living Donor Feedback Members must amend the form or contact the OPTN Contractor to amend this form according to Policy 18.6: Reporting of LiverLiving Donor Adverse Events	72 hours after the donor organ recovery procedure	Any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient
Recovery Hospitals	Living donor registration (LDR)	60 days after the Recovery Hospital submits the <i>living</i> donor feedback form	Each living donor organ recovered at the hospital This does not apply to VCA donor organs
Recovery Hospitals	Living donor follow-up (LDF)	60 days after the six- month, 1-year, and 2-year anniversary of the donation date	Each living donor organ recovered at the hospital This does not apply to VCA, domino donor, and non-domino therapeutic donor organs

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For:
Transplant hospitals	Organ specific transplant recipient follow-up (TRF)	Either of the following: 30 days after the sixmonth and annual anniversary of the transplant date until the recipient's death or graft failure 14 days from notification of the recipient's death or graft failure	Each recipient followed by the hospital
Transplant hospitals	Organ specific transplant recipient registration (TRR)	60 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital
Transplant hospitals	Liver Post-Transplant Explant Pathology	60 days after transplant hospital submits the recipient feedback form	Each liver recipient transplanted by the hospital
Transplant hospitals	Recipient feedback	1 day after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	Candidate Removal Worksheet	1 day after the transplant	Each VCA recipient transplanted by the hospital
Transplant hospitals	Recipient malignancy (PTM)	30 days after the transplant hospital reports the malignancy on the transplant recipient follow-up form	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital
Transplant hospitals	Transplant candidate registration (TCR)	30 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, or pancreas candidate on the waiting list or recipient transplanted by the hospital