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

Policy/Bylaws Affected: **Policies 4.10 (Reference Tables of HLA Antigen Values and Split Equivalences), 5 (Organ Offers, Acceptance, and Verification), and 14.2.B (ILDA Protocols for Living Donor Recovery Hospitals)**

Public Comment: **N/A**

Effective Date: **April 14, 2016**

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 reviewed and approved the clerical changes outlined below retrospectively during their meeting on December 6, 2016.

Summary of Changes

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

Clerical Change	Reason
Policy 4.10, Table 4-3	Table 4-3: HLA B Matching Antigen Equivalences did not have a colon in the table caption. Added colon for consistency; no policy language was affected.
Policy 5, Tables 5-1, 5-2, and 5-3	Incorrect caption numbers needed to be updated. Table numbers were updated only; no policy language was affected.
Policy 14.2.B	Added a period to the end of item #1 in list of ILDA protocol requirements for consistency.

What Members Need to Do

These clerical changes were prospectively implemented on April 14, 2016; 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~~).

Table 4-3: HLA B Matching Antigen Equivalences

Patient B Locus Antigen	Equivalent Donor Antigens
5	5
7	7, 0702
0702	0702, 7
8	8
0802	0802
0803	0803
0804	0804
12	12
13	13, 1301, 1302
1301	1301, 13
1302	1302, 13
14	14
1401	1401, 64
1402	1402, 65
15	15
1501	1501, 62
1502	1502, 75
1503	1503, 72
1510	1510, 71
1511	1511, 75
1512	1512, 76
1513	1513, 77
1516	1516, 63
1517	1517, 63
16	16
17	17
18	18
21	21
22	22
27	27, 2705
2705	2705, 27
2708	2708
35	35
37	37
38	38
39	39, 3901, 3902, 3905, 3913
3901	3901, 39
3902	3902, 39
3905	3905, 39
3913	3913, 39
40	40
4001	4001, 60
4002	4002, 61
4005	4005, 50
4006	4006, 61
41	41
42	42
44	44, 4402, 4403
4402	4402, 44
4403	4403, 44
4415	4415, 45
45	45, 4415
46	46
47	47
48	48
49	49
50	50, 4005
51	51, 5101, 5102
5101	5101, 51
5102	5102, 51
52	52
53	53
54	54
55	55
56	56
57	57, 5701, 5703
5701	5701, 57
5703	5703, 57
58	58
59	59
60	60, 4001
61	61, 4002, 4006
62	62, 1501
63	63, 1516, 1517
64	64, 1401
65	65, 1402
67	67
70	70
71	71, 1510
72	72, 1503
73	73
75	75, 1502, 1511
76	76, 1512
77	77, 1513
78	78
81	81
82	82

5.3.B Infectious Disease Screening Criteria

A transplant hospital may specify whether a candidate is willing to accept an organ from a donor known to have certain infectious diseases, according to *Table 5-1* below:

Table 5.-1: Donor Infectious Disease Screening Options

If the donor tests positive for:	Then candidates may choose not to receive offers on the following match runs:
Cytomegalovirus (CMV)	Intestine
Hepatitis B core antibody (HBcAb)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis B Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C (HCV) Antibody	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Human Immunodeficiency Virus (HIV); Organs from HIV positive donors may only be recovered and transplanted according to the requirements in the Final Rule.	Kidney, Liver; Use of HIV positive donor organs is only permissible for kidney and liver transplantation at this time.

5.8.A Pre-Transplant Verification Prior to Organ Receipt

If the recipient surgery will begin prior to organ receipt in the operating room, the transplant hospital must conduct a pre-transplant verification that meets *all* of the following requirements:

1. Two licensed health care professionals must participate in the verification
2. The intended recipient must be present in the operating room
3. The verification must occur *either*:
   a. Prior to induction of general anesthesia
   b. Prior to incision if the patient has been receiving continuous sedation prior to arrival in the operating room
4. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification prior to organ receipt to verify all of the following information in *Table 5.1 -2* below. Assistance using an OPTN-approved electronic method is permitted.

Table 5.1-2: Pre-Transplant Verification Prior to Organ Receipt Requirements

The transplant hospital must verify all of the following information:	Using at least *one* of these sources:
Expected donor ID	• OPTN computer system • Recipient medical record
Expected organ (and laterality if applicable)	• OPTN computer system • Recipient medical record
Expected donor blood type and subtype (if used for allocation)	• Donor blood type and subtype source documents

The transplant hospital must verify all of the following information:	Using at least *one* of these sources:
	• OPTN computer system
Recipient unique identifier	• Recipient identification band
Recipient blood type	• Recipient blood type and subtype source documents • Recipient medical record
Expected donor and recipient are blood type compatible (or intended incompatible).	• OPTN computer system • Recipient medical record • Attestation following verification of donor and recipient blood types

If a pre-transplant verification was conducted prior to organ receipt, the transplant hospital must document that the verification was completed according to the hospital's protocol and the above requirements.

5.8.B Pre-Transplant Verification Upon Organ Receipt

At the time of organ receipt in the operating room, the transplant hospital must conduct a pre-transplant verification with the following requirements:

1. The transplant surgeon and another licensed health care professional must participate in the verification
2. The intended recipient must be present in the operating room
3. The verification must occur after the organ arrives in the operating room, but prior to anastomosis of the first organ
4. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification upon organ receipt to verify all of the following information in *Table 5.2-3* below. Assistance using an OPTN-approved electronic method is permitted

Table 5.2-3: Pre-Transplant Verification Upon Organ Receipt Requirements

The transplant hospital must verify all of the following information:	Using at least *one* of these sources:
Donor ID	• External and internal organ package labels • Documentation with organ
Organ (and laterality if applicable)	• Organ received
Donor blood type and subtype (if used for allocation)	• Donor blood type and subtype source documents
Recipient unique identifier	• Recipient identification band
Recipient blood type	• Recipient blood type source documents • Recipient medical record
Donor and recipient are blood type compatible (or intended incompatible)	• OPTN computer system • Recipient medical record • Attestation following verification of donor

The transplant hospital must verify all of the following information:	Using at least *one* of these sources:
	and recipient blood types
Correct donor organ has been identified for the correct recipient	• Recipient medical record • OPTN computer system

The transplant hospital must document that the pre-transplant verification upon organ receipt was completed according to the hospital's protocol and the above requirements.

14.2.A ILDA Requirements for Living Donor Recovery Hospitals

Living donor ILDA requirements apply to living kidney, liver, pancreas, intestine or lung donors. For any living kidney donor who is undergoing evaluation for donation, the living donor recovery hospital must designate and provide each living donor with an ILDA who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient. The ILDA may be one person or an independent living donor advocate team with multiple members. An ILDA team must designate one person from the team as the key contact for each living donor.

The ILDA must:

1. Function independently from the transplant candidate's team.
2. Advocate for the rights of the living donor.
3. Fulfill the qualification and training requirements specified in the recovery hospital's protocols regarding knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressure on the living donor's decision about whether to donate. Document that each requirement has been met.
4. Review whether the living donor has received information on each of the following areas and assist the donor in obtaining additional information from other professionals as needed about the:
    a. Informed consent process as described in *Policy 14.3: Informed Consent Requirements*
    b. Evaluation process according to *Policies 14.1.A: Living Donor Psychosocial Evaluation Requirements* and *14.4.B: Living Donor Medical Evaluation Requirements*
    c. Surgical procedure
    d. Medical risks according to *Tables 14-1* through *14-5*
    e. Psychosocial risks according to *Tables 14-1* through *14-5*
    f. Follow-up requirements, and the benefit and need for participating in follow-up according to *Policies 18.1: Data Submission Requirements, 18.5.A: Reporting Requirements after Living Kidney Donation* and *18.5.C: Submission of Living Donor Death and Organ Failur*e
5. Document that each topic was reviewed.