At-a-Glance

Policy Rewrite Parking Lot "Quick Fixes"

- **Affected/Proposed Policy:** Policies 1 (Administrative Rules and Definitions), 2.5 (Hemodilution Assessment), 2.7.B (Informing Personnel), 2.9 (Required Deceased Donor Infectious Testing), 2.11.A (Required Information for Deceased Kidney Donors), 2.14 (Deceased Donor Management), 3.6.B.i (Non-function of a Transplanted Kidney), 3.8.B (Removing Pancreas Islets Candidates from the Waiting List), 5.3.A (Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA)), 5.4.C (Liver Offers), 5.4.E (Backup Organ Offers), 8.2.B (Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings), 8.3 (Points), 9.1.A (Adult Status 1A Requirements), 9.1.B (Pediatric Status 1A Requirements), 9.1.C (Pediatric Status 1B), 9.1.D (MELD Score), 9.1.F (Liver-Intestine Candidates), 9.3.D (Specific MELD/PELD Exceptions), 9.3.F (Candidates with Cholangiocarcinoma), 9.3.G.iii (Recommended Minimum Specifications for Dynamic Contrast-enhanced CT or MRI of the Liver), 9.3.G.iv (Imaging Requirements for Class 5 Lesions), 9.3.G.ix (Compliance Monitoring), 9.5 (Points), 9.5.A (Points for Waiting Time), 9.6.H (Allocation of Liver-Intestines), 9.7.C (Rights Conferred by the Allocation System), 11.2 (Points), 14.3 (Informed Consent Requirements), 14.3.A.ii (Living Kidney Donor Informed Consent Requirements), 14.7.B (Placement of Non-directed Living Donor Kidneys), 14.8 (Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials), 15.1 (Patient Safety Contact), 15.2 (Potential Candidate Screening Requirements), 15.4.B (Requirements for Living Donor Recovery Hospital and Host OPOs), 16.2 (Organs Recovered by Living Donor Recovery Hospitals), 18.1 (Data Submission Requirements), 18.2 (Timely Collection of Data), 19.9 (Access to Recipient Outcomes Data), 20.2.A (Booking Travel), 20.4.B (Transportation To and From the Airport), 20.4.C (Rental Cars), 20.8.A (Expense Reimbursement Form), 20.8.B (Receipts)

- **Policy Oversight Committee (POC)**

  In 2013 the POC sponsored the OPTN Policies Plain Language Rewrite, which was passed by the Board and, the rewritten Policies became effective February 1, 2014. The plain language rewrite included plain language changes and reorganization only, and did not make any substantive changes to the Policies. As a result, during the rewrite, the many reviewers identified a number of issues that would require substantive changes to the Polices; these issues were recorded in the rewrite "parking lot" to be addressed in the future.

  This proposal identifies the "quick fixes" or easy, non-controversial changes that are currently in the rewrite parking lot and offers the corrected policy language to further clarify the OPTN Policies.

- **Affected Groups**
  Directors of Organ Procurement
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators

Transplant Physicians/Surgeons
Transplant Program Directors
Organ Recipients
Organ Candidates
Living Donors
Donor Family Members
General Public

- **Compliance with OPTN Strategic Plan and Final Rule**
  By further clarifying these policies, the proposal supports the strategic plan goal to promote the efficient management of the OPTN. Since it will also enhance understanding and compliance, the proposed improvements to policy language could increase patient safety.

- **Specific Requests for Comment**
  The Committee invites comment on whether the proposed language is more easily understood and whether these substantive changes are appropriate. In particular, the Committee request comment on the sections of policies 1.4, 2.5, 2.7, 9.3, and 20, where "should" was changed to "must" and therefore are now requirements rather than recommendations.

Policy Rewrite Parking Lot "Quick Fixes"

Affected/Proposed Policy:
Policies 1 (Administrative Rules and Definitions), 2.5 (Hemodilution Assessment), 2.7.B (Informing Personnel), 2.9 (Required Deceased Donor Infectious Testing), 2.11.A (Required Information for Deceased Kidney Donors), 2.14 (Deceased Donor Management), 3.6.B.i (Non-function of a Transplanted Kidney), 3.8.B (Removing Pancreas Islets Candidates from the Waiting List), 5.3.A (Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA)), 5.4.C (Liver Offers), 5.4.E (Backup Organ Offers), 8.2.B (Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings), 8.3 (Points), 9.1.A (Adult Status 1A Requirements), 9.1.B (Pediatric Status 1A Requirements), 9.1.C (Pediatric Status 1B), 9.1.D (MELD Score), 9.1.F (Liver-Intestine Candidates), 9.3.D (Specific MELD/PELD Exceptions), 9.3.F (Candidates with Cholangiocarcinoma), 9.3.G.iii (Recommended Minimum Specifications for Dynamic Contrast-enhanced CT or MRI of the Liver), 9.3.G.iv (Imaging Requirements for Class 5 Lesions), 9.3.G.ix (Compliance Monitoring), 9.5 (Points), 9.5.A (Points for Waiting Time), 9.6.H (Allocation of Liver-Intestines), 9.7.C (Rights Conferred by the Allocation System), 11.2 (Points), 14.3 (Informed Consent Requirements), 14.3.A.ii (Living Kidney Donor Informed Consent Requirements), 14.7.B (Placement of Non-directed Living Donor Kidneys), 14.8 (Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials), 15.1 (Patient Safety Contact), 15.2 (Potential Candidate Screening Requirements), 15.4.B (Requirements for Living Donor Recovery Hospital and Host OPOs), 16.2 (Organs Recovered by Living Donor Recovery Hospitals), 18.1 (Data Submission Requirements), 18.2 (Timely Collection of Data), 19.9 (Access to Recipient Outcomes Data), 20.2.A (Booking Travel), 20.4.B (Transportation To and From the Airport), 20.4.C (Rental Cars), 20.8.A (Expense Reimbursement Form), 20.8.B (Receipts)

Policy Oversight Committee (POC)

Public comment response period: September 29 – December 5, 2014

Summary and Goals of the Proposal:

In 2013 the POC sponsored the OPTN Policies Plain Language Rewrite, which was passed by the Board and subsequently, the rewritten Policies became effective February 1, 2014[1]. The plain language rewrite included plain language changes and reorganization only, and did not make any substantive changes to the Policies. As a result, during the rewrite, the many reviewers identified a number of issues that would require substantive changes to the Polices; these issues were recorded in the rewrite "parking lot" to be addressed in the future.

This proposal identifies the "quick fixes" or easy, non-controversial changes that are currently in the parking lot and offers the corrected policy language to further clarify the OPTN Policies.

Background and Significance of the Proposal:
In 2013 the POC sponsored the OPTN Policies Plain Language Rewrite, which was passed by the Board and, the rewritten Policies became effective February 1, 2014. The plain language rewrite included plain language changes and reorganization only, and did not make any substantive changes to the Policies. As a result, during the rewrite, the many reviewers identified

[1] See *OPTN Policies Plain Language Rewrite Policy Notice*

a number of issues that would require substantive changes to the Polices; these issues were recorded in the rewrite "parking lot" to be addressed in the future.

> This proposal identifies the "quick fixes" or easy, non-controversial changes that are currently in the rewrite parking lot and offers the corrected policy language to further clarify the OPTN Policies.

- **Collaboration:** UNOS staff collaborated to identify the quick fixes and possible corrections to the Policies. Drafts of the parking lot proposed changes were circulated to all the OPTN/UNOS Committees and their comments and concerns were discussed and addressed by staff and the POC.

- **Alternatives considered:** The Committee explored the idea of waiting and addressing these issues as part of other projects the Committees are working on or to wait and address all the parking lot issues at one time. However, the POC recognized that these non-controversial quick fixes could be easily made and would clarify Policies for members so there was no benefit to waiting.

  Prior to the 2013 plain language rewrite, members frequently asked whether a policy was a requirement or a recommendation. The 2013 rewrite, therefore, attempted to distinguish between member requirements and recommendations. Policy language was standardized to use "must" for requirements and "should" for recommendations. These recommendations were left in the 2013 plain language rewrite with the intention to further clarify them at a later time, especially given that the goal of the plain language rewrite was to not make substantive changes to the policies. Options to address these recommendations included converting them into requirements (using "must" instead of "should") or clarifying the conditions when they are requirements (e.g., instead of writing that something *should* occur, write that it *must occur in certain situations*). This proposal has both of these solutions.

- **Strengths and weaknesses:** This proposal's strength is that it further clarifies the OPTN Policies. The proposal's weakness is that there are still outstanding issues that remain in the parking lot and will need to be assigned to the appropriate Committee to better address.

- **Description of intended and unintended consequences:** An intended consequence of the Committee is that these clarified policies will address issues identified by reviewers during the 2013 OPTN Policies plain language rewrite and further clarify Policies for members.

Supporting Evidence and/or Modeling:

The 2013 OPTN Policies Plain Language Rewrite identified issues with the current policies and highlighted the need to clarify language but many of those requested clarifications and changes would require substantive changes to the Policies that were not part of the scope of the Plain Language Rewrite. Some of these issues can now be addressed in this proposal as simple, non-controversial, substantive changes that will be approved as part of the typical policy development process, including public comment.

Specifically, the following changes were made:

- Changed "shoulds" to "must" where applicable and when the policy was able to be identified as a true requirement and not just a recommendation
- Standardized periods, including stating periods in days rather than weeks or months

- Streamlined the administrative rules and definitions, including the deletion of unnecessary or duplicative definitions.
- Made necessary changes to more consistently and appropriately use common terms in policies (for example, the use of transplant program versus transplant hospital or transplant center).
- Made simple, non-controversial changes to increase language clarity
- Made some headings more descriptive
- Clarified policy 9.1. (Status Scores and Assignments) by reorganizing lists
- Deleted 9.6.H (Allocation of Liver-Intestines) since it is a repeat of language in 9.1.F (Liver-Intestine Candidates)
- Deleted other outdated or superfluous sections including 9.7.C (Rights Conferred by the Allocation System) and 11.2 (Points)
- Made minor clerical and punctuation changes, including formatting

Expected Impact on Living Donors or Living Donation:

The proposed changes to policies 14.3 (Informed Consent Requirements), 14.3.A.ii (Living Kidney Donor Informed Consent Requirements), 14.7.B (Placement of Non-directed Living Donor Kidneys), and 14.8 (Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials) will improve members' understanding of the requirements for living donors and therefore may increase the safety of living donor transplants.

Expected Impact on Specific Patient Populations:
This proposed policy change will not directly impact any specific patient population.

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule:

By further clarifying the OPTN Policies, the proposal supports the strategic plan goal to promote the efficient management of the OPTN. This proposal also supports the specific strategy to improve readability of OPTN rules and requirements.

Plan for Evaluating the Proposal:

The Committee will continue communication with Regional Administration, Evaluation and Quality, and Membership to determine if members have questions or concerns about the new policy language.

Additional Data Collection:

There is no additional data collection required as a result of this policy change.

Expected Implementation Plan:

If public comment is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015 and, if approved, the clarified policies will become effective in September 2015.

Communication and Education Plan:

The following Communication & Education Activities will help notify members of the clarified policy language and will highlight the specific changes made to the policy language:

- Policy notice
- Presentation at Regional Meetings

Compliance Monitoring:
This proposal does not require any changes to the current compliance monitoring of these policy requirements.

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

Policy 1: Administrative Rules and Definitions

1.1.A Time

A day ends at midnight Eastern Standard Time (EST).

~~1.1.B Gender~~

~~A word used in the masculine includes the feminine.~~

1.1.~~C~~B Headings, Notes, and History

~~The~~ All headings, ~~as well as the~~ notes, and history sections of these Policies, are intended only as guidance and to supplement the OPTN Policies and are not part of the Policies. These sections and headings are nonbinding to members and should not be treated as policy or used to infer the intent of the Policies.

1.1.~~D~~C Reporting of Information to the OPTN Contractor

Members must report requested information to the OPTN Contractor to fulfill membership requirements and to ensure compliance with OPTN Policies and Bylaws. The OPTN Contractor will determine the required method and format for reporting any information required by OPTN Policies and Bylaws, including the requirement to submit specific forms at defined times.

1.2 Definitions

H

Histocompatibility Laboratory
A histocompatibility laboratory is a member of the OPTN. A histocompatibility laboratory member is any histocompatibility laboratory that performs histocompatibility testing, including but not limited to, Human Leukocyte Antigen (HLA) typing, antibody screening, compatibility testing, or crossmatching, and serves at least one transplant hospital member or OPO. Histocompatibility laboratory members are either independent or hospital-based. See also Independent Histocompatibility Laboratory and Hospital-based Histocompatibility Laboratory definitions in the *OPTN Bylaws*.

M

Match run
A ~~procedure~~ process that filters and ranks waiting list candidates based on deceased or non-directed living donor and candidate medical compatibility and organ-specific allocation criteria. A match run is also used to generate a set of potential exchanges for a KPD donor and candidate.

R

Receiving transplant program
The transplant program that receives a deceased or living donor organ from an OPO, transplant hospital, or recovery hospital.

Recipient
A candidate that has received an organ transplant.

~~**Recipient transplant hospitals**~~
~~Transplant hospitals that perform living donor transplants.~~

Recovery hospital
A healthcare facility that recovers living donor organs.

Z

Zero antigen mismatch
A candidate is considered a zero antigen mismatch with a deceased or living donor if *all* of the following conditions are met:

1. At least one donor antigen is identified for each of the A, B, and DR loci
2. At least one candidate antigen is identified for each of the A, B, and DR loci
3. The donor has zero non-equivalent A, B, or DR antigens with the candidate's antigens
4. The donor and the candidate have compatible or permissible blood types

In cases where a candidate or donor has only one antigen identified at an HLA locus (A, B, or DR), the antigens are considered to be identical at that locus. A zero-antigen mismatch may also be referred to as a zero mismatch or 0-ABDR mismatch.

1.4.D Telecommunications Outage

If the OPTN Contractor and members cannot communicate through telephone, affected members:

1. ~~Should~~ Must contact the OPTN Contractor by e-mail to determine operating procedures and to obtain assistance.
2. ~~Should~~ Must continue to use the OPTN computer match program for organ allocation and distribution.
3. Must document and report to the OPTN Contractor any variations in allocation or distribution during the telecommunications problems.

1.4.E OPTN Computer Match Program Outages

If the OPTN Contractor and members cannot communicate by any method and the OPTN computer match program is either not accessible or not operational, affected OPOs:

1. ~~Should~~ Must refer to recent matches of similar blood type and body size for ranking local transplant candidates.
2. ~~Should~~ Must use local transplant program waiting lists to match the best organ with waiting transplant candidates.
3. Must document and report to the OPTN Contractor their process for allocation during the outage.

Policy 2: Deceased Donor Organ Procurement

2.5 Hemodilution Assessment

OPOs ~~should~~ must use qualified (non-hemodiluted) blood samples for deceased donor serological screening tests if available. If a qualified sample is not available for testing, a hemodiluted sample ~~should~~ may be used for deceased donor screening tests.

If serological testing occurs on a hemodiluted blood sample, the host OPO must treat the deceased donor as presenting an increased risk for disease transmission as specified in the U.S. Public Health Services (PHS) Guideline.

Prior to screening, the host OPO must assess all potential deceased donor blood samples that were obtained for serological screening tests for hemodilution using a U.S. Food and Drug Administration (FDA) approved hemodilution calculation. The host OPO must document in the deceased donor medical record a complete history of all blood products and intravenous fluid transfusions the deceased donor received since admission to the donor hospital.

Additionally, the host OPO must report *all* of the following to the accepting transplant programs when a hemodiluted specimen is used in deceased donor screening tests:

1. Any screening results from the hemodiluted specimens.
2. The tests completed on the hemodiluted specimens.
3. The hemodilution calculation used for the hemodiluted specimens, if requested.

2.7.B Informing Personnel

The host OPO ~~should~~ must only inform health-care personnel caring for potential deceased donors or deceased donors who test positive for HIV ~~only~~ when it is necessary for making medical decisions.

2.9.A Kidney

With each kidney offer, the host OPO should provide the ~~recipient transplant hospital~~ receiving transplant program with the following biopsy information for kidneys with a Kidney Donor Profile Index (KDPI) score greater than 85%, and for all other kidneys at the request of the accepting surgeon:

1. Wedge biopsy with the sample measuring approximately 10 mm (length) by 5 mm (width) and 5 mm (depth)
2. A sample that captures a minimum of 25 glomeruli
3. A frozen or fixed section slide, or the biopsy material, may accompany the kidney

2.11.A Required Information for Deceased Kidney Donors

The host OPO must provide *all* the following additional information for all deceased donor kidney offers:

1. Date of admission for the current hospitalization
2. Donor name
3. Donor ID
4. Ethnicity
5. Relevant past medical or social history
6. Current history of abdominal injuries and operations
7. Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria
8. Current medication and transfusion history
9. Anatomical description, including number of blood vessels, ureters, and approximate length of each
10. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53 and DQB antigens. The lab is encouraged to report splits for all loci as outlined in *Policy 4: Histocompatibility*.
11. Indications of sepsis
12. Injuries to or abnormalities of ~~the~~ blood vessels, ureters, or kidney
13. Assurance that final blood and urine cultures
14. Final urinalysis
15. Final blood urea nitrogen (BUN) and creatinine
16. Recovery blood pressure and urine output information
17. Recovery medications
18. Type of recovery procedure, flush solution and method, and flush storage solution
19. Warm ischemia time and organ flush characteristics

2.14 Deceased Donor Management

The host OPO must make reasonable efforts to manage the deceased donor by addressing *all* of the following:

1. Maintaining ~~adequate~~ blood pressure for perfusion of vital organs
2. Monitoring vital signs
3. Administering IV therapy or drugs, as required
4. Administering antibiotic therapy, as required
5. Administering and monitoring fluid intake and output

The OPO must document that these efforts were made and report the results to the receiving OPOs or transplant hospitals.

Policy 3: Candidate Registrations, Modifications, and Removals

3.6.B.i Non-function of a Transplanted Kidney

Immediate and permanent non-function of a transplanted kidney is defined as *either*:

- Kidney graft removal within the first 90 days of transplant documented by an operative report of the removal of the transplanted kidney.
- Kidney graft failure within the first 90 days of transplant with documentation that the candidate is either on dialysis or has measured creatinine clearance (CrCl) or calculated glomerular filtration rate (GFR) less than or equal to 20 mL/min ~~on the date that is~~ within 90 days after the candidate's kidney transplant.

Kidney waiting time will be reinstated when the OPTN Contractor receives a completed *Renal Waiting Time Reinstatement Form* and the supporting documentation required above. The Estimated Post Transplant Survival (EPTS) score will also be calculated without interruption. The OPTN Contractor will send a notice of waiting time reinstatement to the transplant hospital involved.

3.8.B Removing Pancreas Islets Candidates from the Waiting List

The transplant ~~center~~ hospital must remove the candidate from the waiting list within 24 hours of the candidate receiving each islet infusion.

Policy 5: Organ Offers, Acceptance, and Verification

5.3.A Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA)

In order to list an unacceptable antigen for a candidate on the waiting list, the transplant ~~hospital~~ program must do at least *one* of the following:

- Define the criteria for unacceptable antigens that are considered as contraindications for transplant. This may include clarification of unacceptable antigens based on solid phase testing, consideration of prior donor antigens or non-self antigens involved in pregnancies, prior blood transfusion, and unexpected positive crossmatches.
- Base unacceptable antigens on laboratory detection of human leukocyte antigen (HLA) specific antibodies using at least one solid phase immunoassay with purified HLA molecules.

Transplant ~~hospitals~~ programs may establish criteria for additional unacceptable antigens including, but not limited to, multiple unexpected positive crossmatches. CPRA will be derived from HLA antigen/allele group and haplotype frequencies for the different racial and ethnic groups in proportion to their representation in the national deceased donor population. CPRA values will be rounded to the nearest one hundredth percentage.

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 *either* occurs:

- A previously accepted liver is later refused because there is a change in ~~specific~~ medical information or infectious disease test results related to the deceased liver donor
- The deceased donor liver has not been allocated within two hours of procurement

~~Any re-execution of the match system for the same deceased donor for other reasons must be retrospectively reviewed by the Regional Review Board (RRB).~~

5.4.E Backup Organ Offers

OPOs may make backup offers for all organs. Transplant ~~hospitals~~ programs must treat backup offers the same as actual organ offers and must respond within one hour of receiving the required deceased donor information for an organ. If a transplant ~~hospital~~ program refuses to consider or does not respond to a backup offer, the offer will be considered refused.

If a transplant ~~hospital~~ program accepts a backup offer, it may later refuse to accept the organ based on medical or logistical criteria. Transplant programs~~hospitals~~ ~~should~~ must be promptly notified of any change in deceased donor status or organ availability.

Policy 8: Allocation of Kidneys

8.2.B Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings

Allocation of deceased donor kidneys is based on the HLA typing identified by the donor histocompatibility laboratory. If the recipient HLA laboratory identifies a different HLA type for the deceased donor, the kidney may be allocated according to the original HLA typing, or the ~~recipient transplant hospital~~ receiving transplant program may reallocate the kidney locally, according to *Policy 8: Allocation of Kidneys*.

8.3 Kidney Allocation Points

Candidates receive points according to *Tables 8-1* and *8-2* below.

Table 8-1: Kidney Points

If the candidate is:	And the following allocation sequence is used:	Then the candidate receives this many points:
Registered for transplant and meets the qualifying criteria described in *Policy 8.4: Waiting Time*	8.5.H, 8.5.I, 8.5.J, or 8.5.K	1/365 points for each day since the qualifying criteria in *Policy 8.4: Waiting Time*
Aged 0-10 at time of match and a 0-ABDR mismatch with the donor	8.5.H, 8.5.I, or 8.5.J	4 points
Aged 11-17 at time of match and a 0-ABDR mismatch with the donor	8.5.H, 8.5.I, or 8.5.J	3 points

Aged 0-10 at time of match and donor has a KDPI score <35%	8.5.H, 8.5.I	1 point
A prior living donor	8.5.H, 8.5.I, or 8.5.J	4 points
Sensitized (CPRA at least 20%)	8.5.H, 8.5.I, or 8.5.J	*See Table 8-2: Points for CPRA*
A single HLA-DR mismatch with the donor*	8.5.H, 8.5.I, or 8.5.J	1 point
A zero HLA-DR mismatch with the donor*	8.5.H, 8.5.I, or 8.5.J	2 points

*Donors with only one antigen identified at an HLA locus (A, B, and DR) are presumed "homozygous" at that locus.

Table 8-2: Points for CPRA

If the candidate's CPRA score is:	Then the candidate receives this many points:
0	0.00
1-9	0.00
10-19	0.00
20-29	0.08
30-39	0.21
40-49	0.34
50-59	0.48
60-69	0.81
70-74	1.09
75-79	1.58
80-84	2.46
85-89	4.05
90-94	6.71
95	10.82
96	12.17
97	17.30
98	24.40
99	50.09
100	202.10

Policy 9: Allocation of Livers and Liver-Intestines

9.1.A Adult Status 1A Requirements

To assign a candidate adult status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN Contractor. A candidate is not registered as status 1A until this form is submitted.

The candidate's transplant program may assign the candidate adult status 1A if *all* the following conditions are met:

1. The candidate is at least 18 years old at the time of registration
2. The candidate has a life expectancy without a liver transplant of less than 7 days and has at least *one* of the following conditions:

   a. Fulminant liver failure, without pre-existing liver disease and currently in the intensive care unit (ICU), defined as the onset of hepatic encephalopathy within ~~8 weeks~~ 56 days of the first signs or symptoms of liver disease, and has at least *one* of the following criteria:
      i. Is ventilator dependent
      ii. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
      iii. Has an international normalized ratio (INR) greater than 2.0

   b. Anhepatic

   c. ~~b.~~ Primary non-function of a transplanted whole liver within 7 days of transplant, with ~~evidenced by at least *one* of the following:~~
      ~~i. Anhepatic~~Aaspartate aminotransferase (AST) greater than or equal to 3,000 U/L and at least *one* of the following:
         - International normalized ratio (INR) greater than or equal to 2.5
         - Arterial pH less than or equal to 7.30
         - Venous pH less than or equal to 7.25
         - Lactate greater than or equal to 4 mmol/L

      All laboratory results reported for the tests required above must be from the same blood draw taken 24 hours to 7 days after the transplant.

   d. ~~c.~~ Primary non-function within 7 days of transplant of a transplanted liver segment from a deceased or living donor, evidenced by at least *one* of the following:
      ~~i. Anhepatic~~
      i. INR greater than or equal to 2.5
      ii. Arterial pH less than or equal to 7.30
      iii. Venous pH less than or equal to 7.25
      iv. Lactate greater than or equal to 4 mmol/L

   e. ~~d.~~ Hepatic artery thrombosis (HAT) within 7 days of transplant, with ~~evidenced by *either* of the following:~~
      ~~i. Anhepatic~~
      ~~ii. A~~aspartate aminotransferase ~~(~~AST~~)~~ greater than or equal to 3,000 U/L and at least *one* of the following:
         - INR greater than or equal to 2.5
         - Arterial pH less than or equal to 7.30
         - Venous pH less than or equal to 7.25
         - Lactate greater than or equal to 4 mmol/L

      All laboratory results reported for ~~any~~ the tests required above must be from the same blood draw taken 24 hours to 7 days after the transplant.

      Candidates with HAT in a transplanted liver within 14 days of transplant not meeting the above criteria will be listed with a MELD of 40.

   f. ~~e.~~ Acute decompensated Wilson's disease

9.1.B Pediatric Status 1A Requirements

To assign a candidate pediatric status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN Contractor. A candidate is not assigned pediatric status 1A until this form is submitted.

The candidate's transplant program may assign the candidate pediatric status 1A if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of initial registration. This includes candidates who are currently 18 years old and greater but remain on the waiting list, or have returned to the waiting list after initial registration.
2. The candidate has at least *one* of the following conditions:

    a. Fulminant liver failure without pre-existing liver disease, defined as the onset of hepatic encephalopathy within ~~8 weeks~~ 56 days of the first signs and symptoms of liver disease and has at least *one* of the following criteria:
        i. Is ventilator dependent
        ii. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
        iii. Has an international normalized ratio (INR) greater than 2.0

    b. Diagnosis of primary non-function of a transplanted liver within 7 days of transplant, evidenced by at least *two* of the following:
        i. Alanine aminotransferase (ALT) greater than or equal to 2,000 U/L
        ii. INR greater than or equal to 2.5
        iii. Total bilirubin greater than or equal to 10 mg/dL
        iv. Acidosis, defined as *one* of the following:
            - Arterial pH less than or equal to 7.30
            - Venous pH less than or equal to 7.25
            - Lactate greater than or equal to 4 mmol/L

        All laboratory results reported for any tests required for the primary non-function of a transplanted liver diagnosis above must be from the same blood draw taken between 24 hours and 7 days after the transplant.

    c. Diagnosis of hepatic artery thrombosis (HAT) in a transplanted liver within 14 days of transplant

    d. Acute decompensated Wilson's disease

9.1.C Pediatric Status 1B Requirements

To assign a candidate pediatric status 1B, the candidate's transplant hospital must submit a *Liver Status 1B Justification Form* to the OPTN Contractor. A candidate is not registered as status 1B until this form is submitted.

The candidate's transplant program may assign the candidate pediatric status 1B if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of initial registration. This includes candidates who are currently 18 years old and greater but remain on the waiting list or have returned to the waiting list after initial registration.
2. The candidate has *one* of the following conditions:

a. The candidate has a biopsy-proven hepatoblastoma without evidence of metastatic disease.

b. The candidate has an organic acidemia or urea cycle defect and a MELD or PELD exception score of 30 points for at least 30 days.

c. Chronic liver disease with a calculated MELD greater than 25 for adolescent candidates 12 to 17 years old, or a calculated PELD greater than 25 for candidates less than 12 years old, and has at least *one* of the following criteria:
   i. Is on a mechanical ventilator
   ii. Has gastrointestinal bleeding requiring at least 30 mL/kg of red blood cell replacement within the previous 24 hours
   iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
   iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension

d. Chronic liver disease and is a combined liver-intestine candidate with an adjusted MELD or PELD score greater than 25 according to *Policy 9.1.F: Liver-Intestine Candidates* and has at least *one* of the following criteria:
   i. Is on a mechanical ventilator
   ii. Has gastrointestinal bleeding requiring at least 10 mL/kg of red blood cell replacement within the previous 24 hours
   iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
   iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension

9.1.D MELD Score

Candidates who are at least 12 years old receive an initial MELD score equal to:

$$0.957 \times \text{Log}_e(\text{creatinine mg/dL}) + 0.378 \times \text{Log}_e(\text{bilirubin mg/dL}) + 1.120 \times \text{Log}_e(\text{INR}) + 0.643$$

Laboratory values less than 1.0 will be set to 1.0 when calculating a candidate's MELD score.

The following candidates will receive a creatinine value of 4.0 mg/dL:

- Candidates with a creatinine value greater than 4.0 mg/dL
- Candidates who received two or more dialysis treatments within the prior ~~week~~ 7 days
- Candidates who received 24 hours of continuous veno-venous hemodialysis (CVVHD) within the prior ~~week~~ seven days

The maximum MELD score is 40. The MELD score derived from this calculation will be rounded to the tenth decimal place and then multiplied by 10.

For candidates with an initial MELD score greater than 11, ~~T~~the MELD score is then re-calculated as follows:

$$\text{MELD} = \text{MELD}_{(i)} + 1.32*(137-\text{Na}) - [0.033*\text{MELD}_{(i)}*(137-\text{Na})]$$

Sodium values less than 125 mmol/L will be set to 125, and values greater than 137 mmol/L will be set to 137.

9.1.E PELD Score

Candidates who are less than 12 years old receive a PELD score equal to:

0.436 (Age (<1 YR.)) – 0.687 x Log_e (albumin g/dL) + 0.480 x Log_e (total bilirubin mg/dL) + 1.857 x Log_e (INR) +0.667 (Growth failure (<- 2 Std. Deviations present))

The PELD score derived from this calculation will be rounded to the tenth decimal place and then multiplied by 10.

Scores for candidates registered for liver transplantation before the candidate's first birthday continue to include the value of 0.436 until the candidate is 24 months old.

Laboratory values less than 1.0 will be set to 1.0 when calculating a candidate's PELD score.

A candidate has growth failure if the candidate is more than two standard deviations below the candidate's expected growth based on age and gender using the most recent Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics pediatric clinical growth chart.

9.1.F Liver-Intestine Candidates

Candidates awaiting a liver-intestine transplant who are registered and active on both waiting lists will automatically receive an additional increase in their MELD or PELD score equivalent to a 10 percentage point increase in risk of 3-month mortality. Candidates less than 18 years old will receive 23 additional points to their calculated MELD or PELD score instead of the 10 percentage point increase. The transplant hospital must ~~verify~~ document in the candidate's medical record the medical justification for the combined liver-intestine transplant and that ~~an intestinal~~ the transplant ~~is required and took place~~ was completed.

9.3.D Specific MELD/PELD Exceptions

Candidates meeting the criteria in *Table 9-2: Specific Standardized MELD/PELD Exceptions* are eligible for MELD or PELD score exceptions that do not require evaluation by the full RRB. The transplant program must submit a request for a specific MELD or PELD score exception with a written narrative that supports the requested score. Additionally, a candidate may receive a higher MELD or PELD score if the RRB has an existing agreement for the diagnosis. These agreements must be renewed on an annual basis.

Table 9-2: Specific Standardized MELD/PELD Exceptions

If the candidate has:	And submits to the OPTN Contractor evidence that includes:	Then the candidate:
Cholangiocarcinoma	The information required according to *Policy 9.3.F: Candidates with Cholangiocarcinoma.*	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.

If the candidate has:	And submits to the OPTN Contractor evidence that includes:	Then the candidate:
Cystic Fibrosis	The candidate has signs of reduced pulmonary function with forced expiratory volume at one second (FEV_1) that falls below 40 percent.	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.
Familial Amyloid Polyneuropathy (FAP)	*All* of the following: 1. Clear diagnosis of FAP. 2. Echocardiogram showing the candidate has an ejection fraction greater than 40 percent. 3. Ambulatory status. 4. Identification of transthyretin (TTR gene) mutation (Val30Met vs. non-Val30Met). 5. Biopsy- proven amyloid in the involved organ.	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.
Hepatic Artery Thrombosis (HAT)	Candidate has HAT within 14 days of transplant but does not meet criteria for status 1A in Policy *9.1.A: Adult Status 1A Requirements*.	Will receive a MELD score of 40.
Hepatocellular Carcinoma (HCC)	The information required according to *Policy 9.3.G: Candidates with Hepatocellular Carcinoma (HCC)*.	*See Policy 9.3.G: Candidates with Hepatocellular Carcinoma (HCC)*.
Hepatopulmonary Syndrome (HPS)	*All* of the following: 1. Clinical evidence of portal hypertension. 2. Evidence of a shunt. 3. PaO_2 less than 60 mmHg on room air. 4. No significant clinical evidence of underlying primary pulmonary disease.	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months that the candidate's PaO_2 remains under 60 mmHg.
Metabolic Disease	The information required according to *Policy 9.3.E: Pediatric Liver Candidates with Metabolic Diseases.*	See *Policy 9.3.E: Pediatric Liver Candidates with Metabolic Diseases.*

If the candidate has:	And submits to the OPTN Contractor evidence that includes:	Then the candidate:
Portopulmonary Hypertension	The candidate has a mean pulmonary arterial pressure (MPAP) below 35 mmHg following intervention. The diagnosis ~~should~~ must also include *all* of the following: 1. Initial mean pulmonary arterial pressure (MPAP) level. 2. Initial pulmonary vascular resistance (PVR) level. 3. Initial transpulmonary gradient to correct for volume overload. 4. Documentation of treatment. 5. Post-treatment MPAP less than 35 mmHg. 6. Post treatment PVR less than 400 dynes/sec/cm^{-5}..	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months if a repeat heart catheterization confirms that the mean pulmonary arterial pressure (MPAP) remains below 35 mmHg.
Primary Hyperoxaluria	The candidate has *all* of the following: 1. Is registered for a combined liver-kidney transplant. 2. Alanine glyoxylate aminotransferase (AGT) deficiency proven by liver biopsy using sample analysis or genetic analysis. 3. Glomerular filtration rate (GFR) less than or equal to 25 mL/min, by six variable Modification of Diet in Renal Disease formula (MDRD6) or direct measurement of iothalamate or iohexol, for ~~six weeks~~ 42 or more days.	Will receive a MELD score of 28 or PELD score of 41; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.

9.3. F Candidates with Cholangiocarcinoma

A candidate will receive the MELD/PELD exception in *Table 9-2: Specific MELD/PELD Exceptions* for cholangiocarcinoma, if the candidate's transplant hospital meets *all* the following qualifications:

1. Submit a written protocol for patient care to the Liver and Intestinal Organ Transplantation Committee that ~~should~~ must include *all* of the following:
   a. Candidate selection criteria
   b. Administration of neoadjuvant therapy before transplantation
   c. Operative staging to exclude any patient with regional hepatic lymph node metastases, intrahepatic metastases, or extrahepatic disease
   d. Any data requested by the Liver and Intestinal Organ Transplantation Committee

2. Document that the candidate meets the diagnostic criteria for hilar CCA with a malignant appearing stricture on cholangiography and *one* of the following:
   a. Biopsy or cytology results demonstrating malignancy
   b. Carbohydrate antigen 19-9 greater than 100 U/mL in absence of cholangitis

c. Aneuploidy
The tumor ~~should~~ must be considered un-resectable because of technical considerations or underlying liver disease.

3. If cross-sectional imaging studies demonstrate a mass, the mass ~~should~~ must be less than three cm.
4. Intrahepatic and extrahepatic metastases ~~should~~ must be excluded by cross-sectional imaging studies of the chest and abdomen at the time of the initial application for the MELD/PELD exception and every three months before the MELD/PELD score increases.
5. Regional hepatic lymph node involvement and peritoneal metastases ~~should~~ must be assessed by operative staging after completion of neoadjuvant therapy and before liver transplantation. Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable to exclude patients with obvious metastases before neo-adjuvant therapy is initiated.
6. Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound, operative or percutaneous approaches) ~~should~~ must be avoided because of the high risk of tumor seeding associated with these procedures.

9.3.G Candidates with Hepatocellular Carcinoma (HCC)

9.3.G.iii ~~Recommended~~ Minimum Specifications for Dynamic Contrast-enhanced CT or MRI of the Liver

CT scans and MRIs performed for a Hepatocellular Carcinoma (HCC) MELD or PELD score exception application ~~should~~ must meet the criteria in *Table 9-3* and *Table 9-4* and must be interpreted by a radiologist at a transplant hospital. If the scan is inadequate or incomplete then the lesion will be classified as OPTN Class 0 and imaging must be repeated or completed to receive an HCC MELD/PELD exception.

Table 9-3: ~~Recommendations~~ Requirements for Dynamic Contrast-enhanced CT of the Liver

Feature:	CT scans ~~should~~ must meet the below specifications:
Scanner type	Multidetector row scanner.
Detector type	Minimum of 8 detector rows and must be able to image the entire liver during brief late arterial phase time window.
Slice thickness	M~~inimum~~aximum of 5 mm reconstructed slice thickness~~;~~. T~~t~~hinner slices are preferable especially if multi-planar reconstructions are performed.
Injector	Power injector, preferably dual chamber injector with saline flush and bolus tracking recommended.
Contrast injection rate	3 mL/sec minimum, better 4-6 mL/sec with minimum of 300 mg I/mL or higher, for dose of 1.5 mL/kg body weight.
Mandatory dynamic phases on contrast-enhanced MDCT	1. Late arterial phase: artery fully enhanced, beginning contrast enhancement of portal vein. 2. Portal venous phase: portal vein enhanced, peak liver parenchymal enhancement, beginning contrast enhancement of hepatic veins. 3. Delayed phase: variable appearance, greater than 120 seconds after initial injection of contrast.
Dynamic phases (Timing)	Use the bolus tracking or timing bolus.

Table 9-4: ~~Recommendations~~ Requirements for Dynamic Contrast-enhanced MRI of the Liver

Feature	MRIs ~~should~~ must meet the below specifications:
Scanner type	1.5T Tesla or greater main magnetic field strength. Low field magnets are not suitable.
Coil type	Phased array multichannel torso coil, unless patient-related factors precludes its use.
Minimum sequences	Pre-contrast and dynamic post gadolinium T1-weighted gradient echo sequence (3D preferable), T2 (with and without fat saturation), T1-weighted in and out of phase imaging.
Injector	Dual chamber power injector with bolus tracking recommended.
Contrast injection rate	2-3 mL/sec of extracellular gadolinium chelate that does not have dominant biliary excretion, preferably resulting in vendor-recommended total dose.
Mandatory dynamic phases on contrast-enhanced MRI	1. Pre-contrast T1W: do not change scan parameters for post contrast imaging. 2. Late arterial phase: artery fully enhanced, beginning contrast enhancement of portal vein. 3. Portal venous phase: portal vein enhanced, peak liver parenchymal enhancement, beginning contrast enhancement of hepatic veins. 4. Delayed phase: variable appearance, greater than 120 seconds after initial injection of contrast.
Dynamic phases (Timing)	The use of the bolus tracking method for timing contrast arrival for late arterial phase imaging is preferable. Portal vein phase images ~~should~~ must be acquired 35 to 55 seconds after initiation of late arterial phase. Delayed phase images ~~should~~ must be acquired 120 to 180 seconds after the initial contrast injection.
Slice thickness	5 mm or less for dynamic series, 8 mm or less for other imaging.
Breath-holding	Maximum length of series requiring breath-holding ~~should~~ must be about 20-seconds with a minimum matrix of 128 x 256. Technologists must understand the importance of patient instruction about breathholding before and during scan.

9.3.G.iv Imaging Requirements for Class 5 Lesions

Nodules found on images of cirrhotic livers are classified according to *Table 9-5*. Use the largest dimension of each tumor to report the size of Hepatocellular Carcinoma (HCC) lesions. Nodules less than 1 cm are indeterminate and cannot be considered for additional priority.

Table 9-5: Classification System for Nodules Seen on Imaging of Cirrhotic Livers

Class	Description
0	Incomplete or technically inadequate study
5A	Must meet *all* of the following: 1. Single nodule ≥ 1 cm and < 2 cm. The maximum diameter of lesions ~~should~~ must be measured on late arterial or portal phase images. 2. Increased contrast enhancement on late arterial phase (relative to hepatic parenchyma). 3. Washout during the later contrast phases and peripheral rim enhancement (capsule/pseudocapsule) on delayed phase *or* a biopsy. (A pre-listing biopsy is not mandatory.)
5A-g (growth)	Must meet *all* of the following: 1. Single nodule ≥ 1 cm and < 2 cm. The maximum diameter of lesions ~~should~~ must be measured on late arterial or portal phase images. 2. Increased contrast enhancement on late arterial phase (relative to hepatic parenchyma). 3. Growth (maximum diameter increase) by 50% or more documented on serial MRI or CT obtained ≤ 6 months apart. Growth criteria do not apply to ablated lesions.
5B	Must meet *all* of the following: 1. Single nodule diameter ≥ 2 cm. and ≤ 5 cm. The maximum diameter of lesions ~~should~~ must be measured on late arterial or portal phase images. 2. Increased contrast enhancement on late hepatic arterial images (relative to hepatic parenchyma). 3. *One* of the following: a. Washout on portal venous/delayed phase. b. Late capsule or pseudocapsule enhancement. c. Growth (maximum diameter increase in the absence of ablative therapy) by 50% or more documented on serial MRI or CT obtained ≤ 6 month apart. Serial imaging and measurements ~~should~~ must be performed on corresponding contrast phases with the same modality preferred. Growth criteria do not apply to previously ablated lesions. d. Biopsy. (A pre-listing biopsy is not mandatory.)
5T (Treated)	Any OPTN Class 5 or biopsy-proven HCC lesion that was automatically approved upon initial application or extension and has subsequently undergone loco-regional treatment. OPTN Class 5T nodules qualify for continued priority points based on the pre-treatment classification of the nodules and are defined as: Past loco-regional treatment for HCC (OPTN Class 5 lesion or biopsy proven prior to ablation). Evidence of persistent/recurrent HCC such as, but not limited to, nodular or crescentic extra-zonal or intra-zonal enhancing tissue on late arterial imaging (relative to hepatic parenchyma) may be present.
5X	Lesions that meet radiologic criteria for HCC but are outside stage T2 as defined above will be considered Class 5X and are not eligible for automatic exception points.

9.3.G.ix Compliance Monitoring

The transplant hospital must maintain documentation of the radiologic characteristics of each OPTN Class 5 nodule. If growth criteria are used to classify a nodule as HCC, the radiology report must contain the prior and current dates of imaging, type of imaging and measurements of the nodule.

For those candidates who receive a liver transplant while receiving additional priority under the HCC exception criteria, the transplant hospital must submit the *Post-Transplant Explant Pathology Form* to the OPTN Contractor within 60 days of transplant. If the pathology report does not show evidence of HCC, the transplant hospital must also submit documentation or imaging studies confirming HCC at the time of assignment. The Liver and Intestinal Organ Transplantation Committee will review a transplant hospital when more than 10 percent of the HCC cases in ~~a~~ one ~~-~~ year ~~period~~ are not supported by the required pathologic confirmation or submission of clinical information.

9.5 Liver Allocation Points

Points are used for sorting liver candidates according to *Policy 9.6.D: Sorting Within Each Classification*.

9.5.A Points for Waiting Time

Points are assigned so that the status 1A or 1B candidate with the longest waiting time receives the most points as follows:

- 10 points for the candidate with the greatest total status 1A or status 1B ~~W~~waiting ~~T~~time within each classification
- A fraction of 10 points divided up among the remaining status 1A or status 1B candidates within each classification, based on the potential recipient's total waiting time

~~**9.6.H Allocation of Liver-Intestines**~~

~~Adult candidates awaiting a combined liver-intestine transplant who are registered and active on both waiting lists will automatically receive an additional increase in their MELD/PELD score equivalent to a 10% risk of 3-month mortality. Candidates less than 18 years old will receive 23 additional points to their calculated MELD/PELD score instead of the 10% increase. The transplant hospital must verify that an intestinal transplant is required and took place.~~

~~**9.7.C Rights Conferred by the Allocation System**~~

~~No individual or property rights are conferred by the liver allocation system.~~

Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets

~~11.2 Points~~

~~No allocation priority is assigned to pancreas, kidney-pancreas, or islet candidates based on points.~~

Policy 14: Living Donation

14.3 Informed Consent Requirements

~~Education is important so that the potential living donor understands all aspects of the donation process, especially the risks and benefits.~~

14.3.A.ii Living Kidney Donor Informed Consent Requirements

The kidney recovery hospital must obtain informed consent from any potential living kidney donor that ~~must~~ includes written assurance by the potential living donor of *all* of the following:

1. That the potential donor is willing to donate.
2. That the potential donor is free from inducement and coercion.
3. That the potential donor has been informed that the potential living donor may decline to donate at any time.

The potential living donors must be offered an opportunity to stop the donor consent or evaluation process and to do so in a way that is protected and confidential. The ILDA must be available to assist the potential living donor during this process, according to *Policy 14.2*.

The kidney recovery hospital must document in the potential donor's medical record that the hospital provided the potential donor with *all* of the following:

1. Instruction about all phases of the living donation process, including consent, medical, and psychosocial evaluations, pre- and post-operative care, and required post-operative follow up according to *Policy 18.5: Living Donor*. Teaching or instructional material may include any media, or one-on-one or small group interaction. Teaching or instruction must be provided in a language in which the potential living donor is able to engage in a meaningful dialogue with the transplant program recovery hospital's staff.
2. The disclosure that the recovery hospital will take all reasonable precautions to maintain confidentiality for the potential living donor and recipient.
3. The disclosure that it is a federal crime for any person to knowingly acquire, obtain, or otherwise transfer any human organ for anything of value, including, but not limited, to cash, property, and vacations.
4. Disclosure that the recovery hospitals must provide an ILDA.
5. The transplant recipient outcome and transplanted kidney survival data according to *Table 14-1* that follows:

Table 14-1: Required Recipient Outcome and Transplanted Kidney Survival Data

If the recovery hospital and the recipient hospital:	Then:	Including *all* the following information:
Are the same	The recovery hospital must provide the potential living donor with both national and that hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) program~~hospital~~-specific reports.	1. National 1-year patient and transplanted kidney survival 2. The hospital's 1-year patient and transplanted kidney survival 3. Notification about all Centers for Medicare and Medicaid Services (CMS) outcome requirements not being met by the transplant hospital
Will not be the same and the recipient hospital is known	The recovery hospital must provide the potential living donor with both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR program~~hospital~~-specific reports.	4. National 1-year patient and transplanted kidney survival 5. The recipient hospital's 1-year patient and transplanted kidney survival 6. Notification about all CMS outcome requirements not being met by the recipient hospital

6. Education about expected post-donation kidney function, and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the living donor in the future, to include:

    a. On average, living donors may have a 25-35% permanent loss of kidney function after donation.
    b. Baseline risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile.
    c. Living donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occurs, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young potential living donor cannot predict lifetime risk of CKD or ESRD.
    d. Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be faster with only one kidney.
    e. Dialysis is required if the donor develops ESRD.
    Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to *Policy 8.4.F: Prior Living Organ Donor.*
7. The disclosure of alternate procedures or courses of treatment for the recipient, including deceased donor transplantation, and that:

    a. A deceased donor kidney might become available for the recipient before the recovery hospital completes the potential living donor's evaluation or the living donor transplant occurs.

b. Any transplant candidate might have risk factors for increased morbidity or mortality that are not disclosed to the potential living donor.

8. The disclosure that the potential living donor will receive a thorough medical and psychosocial evaluation.

9. The disclosure that health information obtained during the potential living donor's evaluation will be subject to the same regulations as all medical records and could reveal conditions that the transplant hospital must report to local, state, or federal public health authorities.

10. The disclosure that recovery hospitals are required to:

    a. Report living donor follow up information, at the time intervals specified in *Policy 18.5: Living Donor*.
    b. Have the potential living donor commit to post-operative follow up testing coordinated by the living donor recovery hospital.

11. The disclosure that any infectious disease or malignancy pertinent to acute recipient care discovered during the potential living donor's first two years of post-operative follow up care:

    a. Will be disclosed to the living donor
    b. May need to be reported to local, state or federal public health authorities
    c. Will be disclosed to the recipient's transplant hospital
    d. Will be reported to the OPTN Improving Patient Safety Portal.

14.7.B Placement of Non-directed Living Donor Kidneys

Prior to determining the placement of a non-directed living donor kidney, the recovery hospital must obtain the match run of its waiting list candidates from its local OPO or the Organ Center. When a non-directed living donor kidney is allocated, the recovery hospital must document how the organ is allocated and the rationale for allocation.

This requirement does not apply to non-directed living kidney donors who donate a kidney through ~~consent to participate in~~ a Kidney Paired Donation (KPD) arrangement.

14.8 Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials

Recovery hospitals are responsible for packaging and labeling any living donor organs, tissue typing specimens, or vessels that are recovered from living donors according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage* when *either* of the following occurs:

- Living donor organs, tissue typing specimens, or vessels are recovered and must be transported outside the recovery hospital
- A living donor organ, tissue typing specimens, or vessels require~~s~~ repackaging by a transplant hospital for transport outside the transplant hospital

Policy 15: Identification of Transmissible Diseases

15.1 Patient Safety Contact

Each OPO and transplant program must identify a patient safety contact and develop and comply with a written protocol for the patient safety contact to fulfill all the following responsibilities:

1. Be available 24 hours a day.
2. Receive notifications of potential disease transmission and related communication from the OPTN Contractor.
3. Receive relevant medical information that may affect or change recipient care.
4. Communicate any information regarding potential disease transmissions to the medical staff responsible for the recipient's clinical care at the transplant program as soon as possible, but no later than 24 hours after becoming aware of the potential disease transmission.
5. Facilitate communication about the current clinical status of any recipient when the transplant program is notified of a potential or proven disease transmission that may affect the recipient.

~~Transplant programs and OPOs must make this information available to the OPTN Contractor on request.~~

15.2 Potential Candidate Screening Requirements

To be eligible for an organ transplant, potential transplant candidates must be tested for human immunodeficiency virus (HIV), hepatitis B, and hepatitis C, unless the testing would violate state or federal laws. Potential candidates who test positive for HIV, hepatitis B, or hepatitis C ~~should~~ must be offered appropriate counseling.

The OPTN permits HIV test positive individuals as organ candidates if permitted by the transplant hospital. Care of HIV test positive organ candidates and recipients ~~should~~ must not deviate from general medical practice.

15.4.B Requirements for Living Donor Recovery Hospital and Host OPOs

The living donor recovery hospital or host OPO is responsible for *all* the following:

1. Communication of the suspected donor's and affected recipient's test results and diagnosis that may be relevant to acute patient care as soon as possible, but no more than 24 hours after receipt, to any transplant programs, patient safety contacts, and tissue banks that received organs or tissue from the donor. This includes any test results that were not available at the time of procurement or that were performed after recovery. The living donor recovery hospital or host OPO must document that this information is shared with all receiving transplant programs ~~recipient transplant hospitals~~ and tissue banks.

2. Notification of the event to the OPTN Improving Patient Safety Portal as soon as possible, but no later than 24 hours after receipt of test results or diagnosis.

3. Potential disease transmission follow up communication as follows, including:

    a. For deceased donors, completion and submission of the *Potential Disease Transmission Report Form* no later than 24 hours after reporting the event through the OPTN Improving Patient Safety Portal. This must include:
    i. The specific ~~recipient~~ receiving transplant program patient safety contact and tissue bank staff that were notified of the potential transmission
    ii. Disposition of all organs, tissues, and vessels
    iii. Any preliminary information available regarding any remaining deceased donor

samples for additional testing, notification to state or local health department as appropriate for nationally notifiable infectious diseases, and whether an autopsy was performed on the deceased donor.

4. A follow up review of the event, in partnership with OPTN patient safety staff, to determine whether the deceased or living donor was diagnosed with a potentially transmissible disease or condition.

For all living and deceased donors, the Ad Hoc Disease Transmission Advisory Committee may request submission of a *Potential Disease Transmission Donor Follow-Up Report* 45 days after the initial reporting date. Patient safety staff may request additional information related to the living donor beyond 45 days, including pending test results, depending on the potentially transmitted disease or condition.

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 of disease or malignancy, the host OPO must report the information through the OPTN Improving Patient Safety Portal.

If a recovery hospital learns new information about a living donor during the first two years post donation that indicates risk of potential transmission of disease or malignancy, then the recovery hospital must do *at least* ~~*all of*~~ the following:

1. Disclose to the living donor that a potential disease transmission or malignancy must be reported to the ~~recipient transplant hospital~~ receiving transplant program and the OPTN Improving Patient Safety Portal
2. Notify the ~~recipient transplant hospital~~ receiving transplant program
3. Report the potential transmission through the OPTN Improving Patient Safety Portal

The recovery hospital may also need to report the new information to local, state, or federal public health authorities.

Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage

16.2 Organs Recovered by Living Donor Recovery Hospitals

Living donor recovery hospitals must follow all of the requirements for packaging, labeling, and transporting organs, tissue typing material, and vessels according to this Policy, with these differences:

1. While OPOs are responsible for packaging, labeling, and transporting deceased donor organs, vessels, and tissue typing samples, recovery hospitals are responsible for packaging, labeling, and transporting living donor organs, vessels, and tissue typing samples.
2. When a member repackages a living donor organ, they are not required to notify the member that originally packaged the organ.
3. Instead of the list of documents in *Policy 16.5: Documentation Accompanying the Organ or Vessel*, living donor organs must contain the blood type source documents, donor informed consent form, and the complete medical record of the living donor. Vessels that are shipped separately from living donor organs must include the same documents as are required for shipping living donor organs.
4. Blood samples and tissue typing materials must contain the donor ID and *one* of the following three identifiers: donor date of birth, donor initials, or a locally assigned unique ID. Each sample ~~should~~ must contain the donor's blood type and subtype, the type of tissue, and the date and time when the sample was obtained. The recovery hospital must document in the donor record all unique identifiers used to

label blood samples and tissue typing materials.

5. The recovery hospital will provide specimens for tissue typing if requested. The minimum typing materials for living donor kidneys are: two ACD (yellow top) tubes per kidney.

Policy 18 Data Submission Requirements

18.1 Data Submission Requirements

OPOs must provide donor information required for organ placement to the OPTN Contractor in an electronic data format as defined and required by the computer system. Deceased donor information required for organ placement must be submitted prior to organ allocation.

Members must report data to the OPTN using standardized forms. *Table 18-1* shows the member responsible for submitting each data form and when the Mmember must submit the following materials to the OPTN Contractor.

This policy does not apply to VCA-only donors or VCA information for donors and recipients; however, for VCA-only procurements, Host OPOs must submit to the OPTN Contractor the Deceased donor registration (DDR) within 30 days after the procurement date.

Table 18-1: Data Submission Requirements

The following member:	***Must submit the following materials to the OPTN Contractor:***	***Within:***	***For the following groups:***
Histocompatibility Laboratory	*Donor histocompatibility* (DHS)	30 days after the OPO submits the deceased donor registration	For each 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*	For each 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	For all imminent neurological deaths and eligible deaths in its DSA

The following member:	***Must submit the following materials to the OPTN Contractor:***	***Within:***	***For the following groups:***
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	For all deaths reported by a hospital to the OPO
Allocating OPO	*Potential transplant recipient* (PTR)	30 days after the match run date by the OPO or the OPTN Contractor	For each deceased donor organ that is offered to a potential recipient
Host OPO	*Deceased donor feedback*	7 days after the procurement date	
Host OPO	*Deceased donor registration* (DDR)	30 days after the *deceased donor feedback* form is submitted and disposition is reported for all organs	For all deceased donors and authorized but not recovered potential deceased donors
Recovery Hospitals	*Living donor feedback*	The time prior to donation surgery	For each potential living donor organ recovered at the hospital
Recovery Hospitals	*Living donor registration* (LDR)	60 days after the Recovery Hospital submits the *living donor feedback* form	For each living donor organ recovered at the hospital
Recovery Hospitals	*Living donor follow-up* (LDF)	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	For each living donor organ recovered at the hospital
Transplant hospitals	*Organ specific transplant recipient follow-up* (TRF)	<u>*Either* of the following:</u> • 30 days after the six-month 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	For each recipient followed by the hospital

The following member:	***Must submit the following materials to the OPTN Contractor:***	***Within:***	***For the following groups:***
Transplant hospitals	*Organ specific transplant recipient registration* (TRR)	60-_days after transplant hospital submits the *recipient feedback* form	For each recipient transplanted by the hospital
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60-_days after transplant hospital submits the *recipient feedback* form	For each liver recipient transplanted by the hospital
Transplant hospitals	*Recipient feedback*	24-___hours after the transplant	For each 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	For each 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	For each candidate on the waiting list or recipient transplanted by the hospital

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients and living donors is based on recipient or living donor status at a time as close as possible to the specified transplant event anniversary. *Table 18-2: Timely Data Collection* sets standards for when the member must collect the data from the patient.

This policy does not apply to VCA transplants.

Table 18-2: Timely Data Collection

Information is timely if this Member:	**Collects this information for this form:**	**Within this time period:**
Transplant hospital	*Organ specific transplant recipient registration* (TRR)	When the transplant recipient is discharged from the hospital or ~~six weeks~~ 42 days following the transplant date, whichever is first

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Recovery hospital	*Living donor registration* (LDR)	When the living donor is discharged from the hospital or ~~six weeks~~ 42 days following the transplant date, whichever is first
Recovery hospital	*Living donor follow-up* (LDF)	60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date

Policy 19: Data Release

19.9 Access to Recipient Outcomes Data

OPOs may receive recipient outcomes data, without permission from the transplant hospital, for each deceased donor organ transplanted. This information would be used in determining the appropriateness of deceased donor selection and management techniques as well as quality assurance of the procurement process. The data would be accessed and downloaded through the OPTN Contractor. The members that receive the data will not publish or publicly disseminate outcomes of specific recipients, physicians, or institutions. These data fields are located on the *Transplant Recipient Registration* forms and include all of the following:

Recipient status (all organs)

- Living – date of hospital report
- Dead – date and cause of death
- Re-transplanted prior to hospital discharge – date
- Cause of retransplant (thoracic only)

Clinical information at discharge (kidneys only)

- Most recent serum creatinine prior to discharge
- Did kidney produce >40 mL of urine in first 24 hours?
- Did recipient need dialysis within first ~~week~~ 7 days?
- Did creatinine decline by 25% or more in first 24 hours on two separate serum samples taken within first 24 hours?

Transplanted kidney, liver, or pancreas status at discharge

- Functioning or failed
- If failed, date and cause
- Preservation Information (all organs)

Policy 20: Travel Expense and Reimbursement

20.2 Airfare and Rail Reimbursement

20.2.A Booking Travel

OPTN Contractor staff and members must use the approved OPTN Contractor travel agency to arrange all OPTN Contractor related travel and obtain a low-cost coach fare that will accommodate

the traveler's needs. If the traveler chooses not to accept those flight arrangements, the OPTN Contractor will reimburse only up to the amount the approved OPTN travel agency would have paid.

~~Travelers should book airline reservations at least one month in advance of travel.~~

20.4.B Transportation To and From the Airport

The OPTN Contractor will reimburse *all* of the following costs:

1. Transportation between the airport and the traveler's home.
2. Transportation between the airport and the meeting location.
3. Parking fees at the airport from which the traveler departs.

Travelers ~~should~~ must use the least expensive, convenient option to travel to and from airports. The OPTN Contractor will not reimburse limousines unless the cost is shared with another traveler and the total cost to the OPTN Contractor is no more expensive than cab fare.

20.4.C Rental Cars

The OPTN Contractor will not reimburse rental cars if less expensive modes of travel are available. The traveler must elect rental car insurance coverage and ~~should~~ must minimize additional rental car fees. If the traveler elects to rent a car when less expensive modes of travel are available, the OPTN Contractor will reimburse up to the amount of the estimated cab fare needed for the duration of the stay.

20.4.D Provided Ground Transportation

The OPTN Contractor will not reimburse the cost of any other ground transportation if the OPTN Contractor provides ground transportation between an airport and a meeting site and the person traveling could reasonably take advantage of this transportation.

20.8 Filing Expense Reports

20.8.A Expense Reimbursement Form

To request reimbursement from the OPTN Contractor, the traveler must complete and submit an OPTN Contractor expense reimbursement form with original receipts. Off-site OPTN members may submit scanned copies of the original receipts. The traveler must sign the expense reimbursement form and must include *all* of the following information:

1. Dates of travel
2. Reason for travel
3. Meeting location and name of event
4. To whom the reimbursement check will be made payable
5. The address to which the reimbursement will be sent
6. The traveler's phone number

20.8.B Receipts

The expense report must have original receipts for expenses attached. Off-site OPTN members may submit scanned copies of the original receipts. If one traveler has a meal receipt that includes other OPTN Contractor travelers, the receipt must include the names of all travelers.