Notice of Emergency Action

COVID-19 Emergency Policy Package

Sponsoring Committee: Executive
18.1: Data Submission Requirements
18.2: Timely Collection of Data
18.5.A: Reporting Requirements after Living Kidney Donation
18.5.B: Reporting Requirements after Living Liver Donation

Executive Committee Approved: April 3, 2020
Effective Date: Various
Expiration Date: December 31, 2020

Purpose of the Emergency Package
The COVID-19 crisis has created challenges to conducting routine outpatient activities, including clinical testing, which are needed to obtain information required for transplant candidates, recipients, and living donors. The goal of these emergency policies is to suspend or modify certain existing policy requirements due to unforeseen circumstances that prevent patients from reaching the transplant program or other health care facility for needed testing or evaluation. These actions are supported by the emergency pathway provided in OPTN Bylaw 11.7, and will be will be distributed for public comment before September 17, 2020 for a minimum 30-day period. The actions outlined in this notice will be reviewed at every OPTN Executive Committee regularly-scheduled meeting, at a minimum of every three months, until the actions expire December 31, 2020.

Proposal History
This proposal was developed with input from multiple OPTN Committees. It was passed by the Executive Committee on April 3, 2020 using the emergency pathway due to the COVID-19 public health crisis. The Executive Committee has continued to review these actions at their 2020 meetings on April 20, June 7, and July 30. At the July 30, 2020 meeting, the Executive Committee voted to extend the expiration date of the actions due to expire on September 30, 2020. The effective date has been extended to December 31, 2020 due to the continued impacts from the COVID-19 pandemic. The Executive Committee also voted to send this proposal out retrospectively for public comment, August 4 – October 1, 2020, as required by OPTN Bylaw 11.7.

1 The COVID 19 Emergency Policy Package was originally approved by the Executive Committee on April 3, 2020 with an original expiration date of September 30, 2020. On July 30, 2020, the Executive Committee extended the expiration date until December 31, 2020.
Action 1: Modifications to wait time initiation for non-dialysis kidney candidates

Purpose
This policy prevents potential non-dialysis candidates who meet creatinine clearance or glomerular filtration rate (GFR) criteria from being disadvantaged. The COVID-19 public health emergency has created a scenario where a patient with a qualifying GFR, at a program that has decided to register the candidate, may be unable to obtain other testing required for registration. As a result, a candidate would be ready for registration but unable to begin accruing waiting time per Policy 8.4. This emergency policy allows transplant programs to submit a waiting time modification application to retroactively initiate waiting time for affected candidates.

Summary of Changes
A new section of policy was approved. With a completed application, including required documentation, a qualifying candidate will be able to have waiting time “backdated” to the date the program had documented intent to register.

Implementation
The OPTN will promulgate information about the special wait time modification form and will be able to backdate the initiation of wait time, retroactive to April 3, 2020, the effective date of the emergency policy. Transplant hospitals will need to educate their staff about this policy. Additionally, hospitals should develop an internal system to track information regarding these patients until they are ready to register them as candidates.

Action 2: Relax data submission requirements

Purpose
Current OPTN policy requires that transplant programs submit numerous data for transplant recipients and living donors. This emergency policy change relaxes requirements for follow-up form submission. The intent of the policy is to prevent unnecessary exposure risk to transplant recipients and living donors, and also to alleviate data burden for centers in the midst of COVID-19 crisis.

Summary of Changes
This emergency policy suspends the requirements for data collection and submission for the living donor follow-up (LDF), organ specific transplant recipient follow-up (TRF), and recipient malignancy (PTM) forms. The suspension of these requirements is backdated to March 13, 2020 and is scheduled to expire on December 31, 2020.

This will not suspend the requirement to report recipient death or graft failure, but will extend the timeframe for reporting that information for transplant recipients.

Implementation
Transplant programs will need to educate staff to this policy change. The policy is retroactively effective to March 13, 2020, and the OPTN will issue systems notices and other information to explain the user
experience related to affected forms within the system.

**Action 3: Incorporation of COVID-19 infectious disease testing into DonorNet®**

**Purpose**

DonorNet® currently captures information regarding potential infectious diseases identified as a result of testing performed on deceased donors but does not yet include COVID-19. This action adds COVID-19 testing to DonorNet® so accepting centers can see whether donors were tested, and if so what the results were.

**Summary of Changes**

This action authorizes addition of COVID-19 related fields to DonorNet® for OPOs to enter information on testing performed on deceased donors. The fields will be included among the other infectious disease testing fields. Upon implementation, the new data fields will be optional.

**Implementation**

Programming is required to implement these new data elements to DonorNet®. UNOS IT estimates approximately two weeks of work, and will issue applicable system notices when the fields are live for manual data entry from April 3, 2020, the day of passage of the emergency policy. Data definitions will also be promulgated.

**Other Action Considered: Use of Local Recovery Teams for Organ Procurement**

During the meeting in which the above three actions were approved, the Executive Committee considered whether adopting OPTN policy mandating organ recovery by local teams, when possible, was a prudent action in light of the COVID-19 crisis. After discussion, the Executive Committee decided not to issue a policy mandate at this time, but to consider offering official guidance regarding local recovery as the preferred method during this emergency. The draft policy within the associated Mini-Brief was not adopted.

**Affected Policy Language**

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

**3.7.D Applications for Modifications of Kidney Waiting Time during 2020 COVID-19 Emergency**

This emergency policy only applies to candidates whose ability to demonstrate eligibility for kidney waiting time has been compromised by the COVID-19 public health emergency declared by the President of the United States on March 13, 2020.

This emergency policy allows transplant programs to submit a waiting time modification for candidates who were not on regularly administered dialysis and, due to the emergency, were unable to begin accruing waiting time according Policy 8.4.A Waiting Time for Candidates Registered at Age 18 Years or Older or Policy 8.4.B Waiting Time for Candidates Registered prior to Age 18.
To apply for a waiting time modification, the candidate’s transplant program must submit an application to the OPTN with all of the following information:

1. The requested waiting time start date for the candidate. The requested start date must be the date when the transplant program made the decision to register the candidate.
2. Documentation explaining why the circumstances of the COVID-19 public health emergency prevented the candidate from beginning to accrue waiting time according to Policy 8.4.A Waiting Time for Candidates Registered at Age 18 Years or Older or Policy 8.4.B Waiting Time for Candidates Registered prior to Age 18. For candidates registered at age 18 years or older, documentation must include a date prior to the requested start date that the candidate’s measured or calculated creatinine clearance or GFR was less than or equal to 20 mL/min.
3. The name and signature of the candidate’s physician or surgeon.

Upon receipt of a complete application the OPTN will implement the waiting time modification for candidates who were impacted by the COVID-19 emergency.

This subsection supersedes any conflicting requirements in other sections of OPTN Policy for candidates that apply for a waiting time modification pursuant to this subsection.

18.1 Data Submission Requirements

Members must report accurate data to the OPTN using standardized forms 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>
<thead>
<tr>
<th>The following member:</th>
<th>Must submit the following materials to the OPTN:</th>
<th>Within:</th>
<th>For:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Histocompatibility Laboratory</td>
<td>Donor histocompatibility (DHS)</td>
<td>30 days after the OPO submits the deceased donor registration</td>
<td>Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory</td>
</tr>
</tbody>
</table>
| 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 |
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>OPOs, all</td>
<td>Death notification records (DNR)</td>
<td>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</td>
<td>All imminent neurological deaths and eligible deaths in its DSA</td>
</tr>
<tr>
<td>OPOs, all</td>
<td>Monthly Donation Data Report: Reported Deaths</td>
<td>30 days after the end of the month in which a donor hospital reports a death to the OPO</td>
<td>All deaths reported by a hospital to the OPO</td>
</tr>
<tr>
<td>Allocating OPO</td>
<td>Potential transplant recipient (PTR)</td>
<td>30 days after the match run date by the OPO or the OPTN</td>
<td>Each deceased donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient</td>
</tr>
<tr>
<td>Allocating OPO</td>
<td>VCA Candidate List</td>
<td>30 days after the procurement date</td>
<td>Each deceased donor VCA organ that is offered to a potential VCA recipient</td>
</tr>
<tr>
<td>Host OPO</td>
<td>Donor organ disposition (feedback)</td>
<td>5 business days after the procurement date</td>
<td>Individuals, except living donors, from whom at least one organ is recovered</td>
</tr>
<tr>
<td>Host OPO</td>
<td>Deceased donor registration (DDR)</td>
<td>30 days after the donor organ disposition (feedback) form is submitted and disposition is reported for all organs</td>
<td>All deceased donors</td>
</tr>
</tbody>
</table>
| 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 |
<table>
<thead>
<tr>
<th>The following member:</th>
<th>Must submit the following materials to the OPTN:</th>
<th>Within:</th>
<th>For:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recovery Hospitals</td>
<td>Living donor feedback</td>
<td>72 hours after the donor organ recovery procedure</td>
<td>Any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient</td>
</tr>
<tr>
<td></td>
<td>Members must amend the form or contact the OPTN Contractor to amend this form according to Policy 18.6: Reporting of Living Donor Adverse Events</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recovery Hospitals</td>
<td>Living donor registration (LDR)</td>
<td>60 days after the recovery hospital submits the living donor feedback form</td>
<td>Each living donor organ recovered at the hospital</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>This does not apply to VCA donor organs</td>
</tr>
<tr>
<td>Recovery Hospitals</td>
<td>Living donor follow-up (LDF)</td>
<td>Either:</td>
<td>Each living donor organ recovered at the hospital</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date or</td>
<td>This does not apply to VCA, domino donor, and non-domino therapeutic donor organs.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• As determined possible by the transplant hospital during the COVID-19 emergency.</td>
<td>Non-submission of the full LDF is acceptable during the COVID-19 emergency.</td>
</tr>
<tr>
<td>The following member:</td>
<td>Must submit the following materials to the OPTN:</td>
<td>Within:</td>
<td>For:</td>
</tr>
<tr>
<td>----------------------</td>
<td>-------------------------------------------------</td>
<td>---------</td>
<td>------</td>
</tr>
</tbody>
</table>
| Transplant hospitals | *Organ specific transplant recipient follow-up (TRF)* | Either of the following:  
  - 30 days after the six-month and annual anniversary of the transplant date until the recipient’s death or graft failure or as determined possible by the transplant hospital during the COVID-19 emergency.  
  - 1430 days from notification of the recipient’s death or graft failure | Each recipient followed by the hospital  
  Non-submission of the full TRF is acceptable during the COVID-19 emergency; however notifications of recipient’s death or graft failure are still required during the COVID-19 emergency. |
<p>| Transplant hospitals | <em>Organ specific transplant recipient registration (TRR)</em> | 60 days after transplant hospital removes the recipient from the waiting list | Each recipient transplanted by the hospital |
| Transplant hospitals | <em>Liver Post-Transplant Explant Pathology</em> | 60 days after transplant hospital submits the recipient feedback form | Each liver recipient transplanted by the hospital |
| Transplant hospitals | <em>Recipient feedback</em> | 1 day after the transplant | Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital |
| Transplant hospitals | <em>Candidate Removal Worksheet</em> | 1 day after the transplant | Each VCA recipient transplanted by the hospital |</p>
<table>
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<tr>
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<th>Must submit the following materials to the OPTN:</th>
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<th>For:</th>
</tr>
</thead>
</table>
| Transplant hospitals | Recipient malignancy (PTM)                      | Either: | Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital.  
Non-submission is acceptable during the COVID-19 emergency. |
|                      |                                                 | • 30 days after the transplant hospital reports the malignancy on the transplant recipient follow-up form or  
• As determined possible by the transplant hospital during the COVID-19 emergency. |      |

| 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 |

### 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.

**Table 18-2: Timely Data Collection**

<table>
<thead>
<tr>
<th>Information is timely if this Member:</th>
<th>Collects this information for this form:</th>
<th>Within this time period:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transplant hospital</td>
<td>Organ specific transplant recipient registration (TRR)</td>
<td>When the transplant recipient is discharged from the hospital or 42 days following the transplant date, whichever is first.</td>
</tr>
</tbody>
</table>
| Recovery hospital                    | Living donor registration (LDR)        | When the living donor is discharged from the hospital or 42 days following the transplant date, whichever is first.  
This does not apply to VCA transplants. |
18.5 Living Donor Data Submission Requirements

The follow up period for living donors will be a minimum of two years.

The OPTN Contractor will calculate follow-up rates separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.

Living donor follow-up reporting requirements do not apply to any transplant recipient whose replaced or explanted organ is donated to another candidate.

18.5.A Reporting Requirements after Living Kidney Donation

During the COVID-19 emergency, these policy requirements are suspended.

The recovery hospital must report accurate, complete, and timely follow up data for donor status and clinical information using the LDF form for at least:

- 60% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 70% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 80% of their living kidney donors who donate after December 31, 2014
The recovery hospital must report accurate, complete, and timely follow up kidney laboratory data using the LDF form for at least:

- 50% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 60% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 70% of their living kidney donors who donate after December 31, 2014

Required kidney donor status and clinical information includes all of the following:

1. Patient status
2. Working for income, and if not working, reason for not working
3. Loss of medical (health, life) insurance due to donation
4. Has the donor been readmitted since last LDR or LDF form was submitted?
5. Kidney complications
6. Regularly administered dialysis as an ESRD patient
7. Donor developed hypertension requiring medication
8. Diabetes
9. Cause of death, if applicable and known

Required kidney laboratory data includes all of the following:

1. Serum creatinine
2. Urine protein

18.5.B Reporting Requirements after Living Liver Donation

During the COVID-19 emergency, these policy requirements are suspended.

The recovery hospital must report accurate, complete, and timely follow-up data using the LDF form for living liver donors who donate after September 1, 2014, as follows:

1. Donor status and clinical information for 80% of their living liver donors.
2. Liver laboratory data for at least:
   - 75% of their living liver donors on the 6 month LDF
   - 70% of their living liver donors on the one year LDF

Required liver donor status and clinical information includes all of the following:

1. Patient status
2. Cause of death, if applicable and known
3. Working for income, and if not working, reason for not working
4. Loss of medical (health, life) insurance due to donation
5. Hospital readmission since last LDR or LDF was submitted
6. Liver complications, including the specific complications
   - Abscess
   - Bile leak
   - Hepatic resection
   - Incisional hernias due to donation surgery
   - Liver failure
   - Registered on the liver candidate waiting list
Required liver laboratory data includes *all* of the following:

1. Alanine aminotransferase
2. Alkaline phosphatase
3. Platelet count
4. Total bilirubin
**Action 3: Affected Data Fields**

*ADD*: parent question field: “Was COVID-19 (SARS-CoV-2) testing performed on the donor?”

a. Yes/No/Unknown field to allow OPOs to clearly indicate testing status related to COVID-19 (SARS-CoV-2)
   i. If yes:
      1. *ADD* specimen date field
      2. *ADD* time field
      3. *ADD* specimen type field
      4. *ADD* hemodiluted specimen field
      5. *ADD* test method field
      6. *ADD* results field
      7. *ADD* “comments” field - free text box for entry for information relevant to COVID-19 testing (e.g. “results pending”)
   ii. If no: no child data fields will display