

## *Notice of Emergency Action*

# COVID-19 Emergency Policy Package

<b>Sponsoring Committee:</b>	<b>Executive</b>
<b>Policies Affected:</b>	<b><i>3.7.D: Applications for Modification of Kidney Waiting Time during 2020 COVID-19 Emergency</i></b> <b><i>18.1: Data Submission Requirements</i></b> <b><i>18.2: Timely Collection of Data</i></b> <b><i>18.5.A: Reporting Requirements after Living Kidney Donation</i></b> <b><i>18.5.B: Reporting Requirements after Living Liver Donation</i></b>
<b>Executive Committee Approved:</b>	<b>April 3, 2020</b>
<b>Effective Date:</b>	<b>Various</b>
<b>Expiration Date:</b>	<b>December 31, 2020<sup>1</sup></b>

### **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 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.

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<sup>1</sup> 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 18-1: Data Submission Requirements**

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Histocompatibility Laboratory	<i>Donor histocompatibility (DHS)</i>	30 days after the OPO submits the deceased donor registration	Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory
Histocompatibility Laboratory	<i>Recipient histocompatibility (RHS)</i>	<i>Either of the following:</i> <ul style="list-style-type: none"> <li>• 30 days after the transplant hospital removes the candidate from the waiting list because of transplant</li> <li>• 30 days after the transplant hospital submits the <i>recipient feedback</i></li> </ul>	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory

The following member:	Must submit the following materials to the OPTN:	Within:	For:
OPOs, all	<i>Death notification records (DNR)</i>	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	All imminent neurological deaths and eligible deaths in its DSA
OPOs, all	<i>Monthly Donation Data Report: Reported Deaths</i>	30 days after the end of the month in which a donor hospital reports a death to the OPO	All deaths reported by a hospital to the OPO
Allocating OPO	<i>Potential transplant recipient (PTR)</i>	30 days after the match run date by the OPO or the OPTN	Each deceased donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient
Allocating OPO	<i>VCA Candidate List</i>	30 days after the procurement date	Each deceased donor VCA organ that is offered to a potential VCA recipient
Host OPO	<i>Donor organ disposition (feedback)</i>	5 business days after the procurement date	Individuals, except living donors, from whom at least one organ is recovered
Host OPO	<i>Deceased donor registration (DDR)</i>	30 days after the <i>donor organ disposition (feedback)</i> form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	<i>Living donor feedback</i>	The time prior to donation surgery	Each potential living donor organ recovered at the hospital  This does not apply to VCA donor organs

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Recovery Hospitals	<p><i>Living donor feedback</i></p> <p>Members must amend the form or contact the OPTN Contractor to amend this form according to <i>Policy 18.6: Reporting of Living Donor Adverse Events</i></p>	72 hours after the donor organ recovery procedure	Any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient
Recovery Hospitals	<i>Living donor registration (LDR)</i>	60 days after the recovery hospital submits the <i>living donor feedback</i> form	<p>Each living donor organ recovered at the hospital</p> <p>This does not apply to VCA donor organs</p>
Recovery Hospitals	<i>Living donor follow-up (LDF)</i>	<p><u>Either:</u></p> <ul style="list-style-type: none"> <li>• 60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date <u>or</u></li> <li>• <u>As determined possible by the transplant hospital during the COVID-19 emergency.</u></li> </ul>	<p>Each living donor organ recovered at the hospital</p> <p>This does not apply to VCA, domino donor, and non-domino therapeutic donor organs.</p> <p><u>Non-submission of the full LDF is acceptable during the COVID-19 emergency.</u></p>

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Transplant hospitals	<i>Organ specific transplant recipient follow-up (TRF)</i>	Either of the following: <ul style="list-style-type: none"> <li>• 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure <u>or as determined possible by the transplant hospital during the COVID-19 emergency.</u></li> <li>• <u>1430</u> days from notification of the recipient's death or graft failure</li> </ul>	Each recipient followed by the hospital  <u>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.</u>
Transplant hospitals	<i>Organ specific transplant recipient registration (TRR)</i>	60 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital
Transplant hospitals	<i>Liver Post-Transplant Explant Pathology</i>	60 days after transplant hospital submits the <i>recipient feedback</i> form	Each liver recipient transplanted by the hospital
Transplant hospitals	<i>Recipient feedback</i>	1 day after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	<i>Candidate Removal Worksheet</i>	1 day after the transplant	Each VCA recipient transplanted by the hospital

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Transplant hospitals	<i>Recipient malignancy (PTM)</i>	<p><u>Either:</u></p> <ul style="list-style-type: none"> <li>30 days after the transplant hospital reports the malignancy on the <i>transplant recipient follow-up form</i> <u>or</u></li> <li><u>As determined possible by the transplant hospital during the COVID-19 emergency.</u></li> </ul>	<p>Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital.</p> <p><u>Non-submission is acceptable during the COVID-19 emergency.</u></p>
Transplant hospitals	<i>Transplant candidate registration (TCR)</i>	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**

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	<i>Organ specific transplant recipient registration (TRR)</i>	When the transplant recipient is discharged from the hospital or 42 days following the transplant date, whichever is first.
Recovery hospital	<i>Living donor registration (LDR)</i>	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.



Information is timely if this Member:	Collects this information for this form:	Within this time period:
Recovery hospital	<i>Living donor follow-up (LDF)</i>	<p><u>Either:</u></p> <ul style="list-style-type: none"> <li>• 60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date <u>or</u></li> <li>• <u>As determined possible by the transplant hospital during the COVID-19 emergency.</u></li> </ul> <p>This does not apply to VCA transplants.</p> <p><u>Non-submission is acceptable during the COVID-19 emergency.</u></p>

## 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

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## 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

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