

**Maine Medical Center
Maine Transplant Program
Policies and Procedures
Program Inactivity, Withdrawal and Termination Policy**

Policy

It is the policy of the Maine Transplant Program (MTP) to outline the policy and procedures for notifying candidates, potential candidates, recipients and live donors about program closure and short and long term program inactivity in accordance with applicable UNOS Bylaws and CMS Conditions of Participation.

Procedure

TRANSPLANT PROGRAM INACTIVITY

MTP may voluntarily inactivate the program, on a short or long basis, for reasons including but not limited to:

- The inability to meet functional activity requirements (perform a minimum number of transplants: for kidney transplant programs this happens if the program performs below the minimum number of transplants (1) for 3 consecutive months)
- The inability to serve potential candidates, candidates, recipients, potential living donors, or living donors for a period of 15 or more consecutive days
- Temporarily lacking required physician or surgeon coverage
- A substantial change in operations that requires an interruption in transplantation.

PROGRAM COMPONENT CESSATION

If MTP ceases to perform a specific type of transplant (i.e. living donor or cessation of only pediatric or only adult transplants), we will notify every patient affected by the cessation, including:

- Potential candidates, including those currently in the referral or evaluation process
- All candidates registered on the waiting list
- Potential living donors, including those currently in the referral process, in the evaluation process, or awaiting donation

Ceased Component	All Affected Patients Being Treated or Evaluated by MTP Including:
Living Donor Component	<ul style="list-style-type: none"> • Potential Living Donors • Potential and waitlisted candidates who have already expressed interest in LD
Deceased Donor Component	<ul style="list-style-type: none"> • Potential and waitlisted deceased donor candidates
Adult Component	<ul style="list-style-type: none"> • Potential and waitlisted adult candidates • Potential and waitlisted pediatric candidates who may turn 18 during component cessation period
Pediatric Component	<ul style="list-style-type: none"> • Potential and waitlisted pediatric candidates

SHORT-TERM INACTIVE TRANSPLANT PROGRAM STATUS

Short-term inactivity is defined as a transplant program that is inactive for no more than 14 consecutive days. MTP may voluntarily inactivate for no more than 14 days by changing its UNET waiting list status to *inactive*.

Procedure

1. MTP will provide candidates and recipients a written summary of its Program Coverage Plan at the time of listing (see Program Coverage Policy) and any time there is substantial changes in program or personnel. If MTP knows it will have periods of short-term inactivity, it will clearly stated as part of the Program Coverage Plan provided at time of listing.
2. Notification to UNOS is not required if the program chooses to voluntarily inactivate on a short term basis.

LONG TERM INACTIVE TRANSPLANT PROGRAM STATUS

Long term inactivity occurs when a program is inactive for 15 or more consecutive days. MTP will voluntarily inactivate their program if unable to serve potential candidates, living donors or recipients for 15 or more consecutive days. Voluntary inactivation may extend for a period of up to 12 months. Long term inactivation results in an inactive waiting list status and an inactive program status.

Procedure

1. MTP will provide written notice to the OPTN Executive Director outlining the reasons for inactivation.
2. MTP will provide written notice to the program's potential candidates, candidates, recipients, and living donors currently being treated by the program. Written notice will be provided at least 30 days prior to the planned inactivation date by a trackable method that provides proof of receipt such as:
 - Commercial overnight delivery service
 - Secure electronic communication
 - Registered or certified mail, return receipt requested.
3. Written notice will be provided no later than 7 days after inactivation and include all of the following:
 1. The reasons for inactivating the transplant program
 2. Explanation that although the patient is still on the waiting list, the candidate cannot receive an organ offer through this program while it is inactive
 3. Options for potential candidates, candidates, recipients and living donors to transfer to another program
 4. Prior to being registered as an active candidate at another transplant program, the accepting transplant program will complete an evaluation to determine suitability for registration.
 5. The phone number of MTP's administration that can help with transferring to another transplant program.
4. MTP will provide the OPTN with a sample of each type of patient notice it sends to the potential candidates, candidates, recipients, and living donors along with a list of patients who received the notice.

5. If a natural disaster should occur that requires inactivation, patient notification requirements will be applied reasonably and flexibly.

WITHDRAWAL OR TERMINATION OF DESIGNATED TRANSPLANT PROGRAM STATUS

Designated transplant program withdrawal means that the program voluntarily gave up its designated transplant program status (is voluntarily closing the transplant program) and provides written notice to the OPTN Contractor.

Procedure

1. OPTN Notice: MTP will provide written notice to the OPTN Contractor within 30 days of the intent to withdraw its designated program status, including the effective date and reasons for withdrawal.
2. Patient Notice: If MTP were to withdraw its designated transplant program status or its designated transplant program status is terminated, it will provide written notice to the program's potential candidates, candidates, recipients and living donors currently receiving care.
 - a. Written notice will be provided at least 30 days prior to the anticipated date of withdrawal or termination by a method that can be tracked and provides written proof of receipt such as:
 - Commercial overnight delivery service
 - Secure electronic communication
 - Registered or certified mail, return receipt requested
 - b. Written notice will be provided no later than 7 days following withdrawal or termination and include:
 - i. Reasons for loss of designated transplant program status
 - ii. Explanation that although the patient is still on the waiting list, the candidate cannot receive an organ offer through this program
 - iii. Options for potential candidates, candidates, recipients and living donors to transfer to another transplant program
 - iv. Prior to being registered as an active candidate at another transplant program, the accepting transplant program will complete an evaluation to determine suitability for registration
 - v. The phone number of MTPs administrator that can help with transferring the candidate or potential candidate to another program.

MTP will provide the OPTN Contractor with samples of each type of patient notice it sends to potential candidates, candidates, recipients, and living donors along with a

TRANSITION PLAN DURING LONG-TERM INACTIVITY, TERMINATION, OR WITHDRAWAL

If MTP experiences long term inactivity, withdraws its designated transplant program status, or its designated transplant program status is terminated it will:

Procedure:

1. Immediately suspend organ transplantation

2. Assist potential candidates and candidates in transferring to other designated transplant programs
3. Provide a list to the OPTN Contractor of all the transplant program's candidates on the waiting list at the time of the long-term inactivity, withdrawal, or termination and update it throughout this process.

MTP will indicate on the list of candidates if:

- A candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision before they are removed from the waiting list.
- A candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic status updates will be made that document each candidate's transfer progress until the candidate is evaluated and accepted on the waiting list by another transplant program or removed from the waiting list.
 - Expedite removal of all candidates from MTP's waiting list, or if the patient requests, transfer the candidate to another OPTN member transplant hospital
 - Initiate transfer of all active candidates hospitalized at the transplant program to an accepting transplant hospital within 7 days of long-term inactivity, withdrawal, or termination. MTP will complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time, or circumstances outside of MTP's control exist that prevent transfer within 14 days. MTP will document and submit to the OPTN contractor all efforts to transfer its hospitalized candidates, if it is unable to meet these time periods.
 - Provide a priority list of the most urgent candidates listed at MTP with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the priorities outlined in OPTN By Laws Appendix K.5.
 - All active candidates will be transferred within 60 days of long term inactivity, withdrawal, or termination.
 - The program will document all efforts to transfer candidates to alternative programs and submit to the OPTN/UNOS documentation of all efforts made to transfer all candidates if unable to meet the 60 day deadline.
 - The program will remove every candidate from the transplant program waiting list within 12 months of the program's long-term inactivity, withdrawal, or termination date.
 - If ongoing care is provided to candidates, recipients, and living donors during this period, the program will continue to submit all necessary UNOS follow up forms through UNET.

Transferred Candidates Waiting Time

The transfer of candidates waiting time will happen in accordance with OPTN By Laws Appendix K.6, including:

- Patient notification
- Transplant programs written agreements
- Plans for accepting transplant programs

Laboratory Tests

If MTP is inactivated, terminated or withdrawn from OPTN qualified transplant program membership, it will still be responsible for evaluating its candidates as per OPTN by laws. This includes, but is not limited to, performing laboratory tests and evaluations required to maintain the candidates' appropriate status on the waiting list until the time of transfer.

CMS Notification

The Transplant Program will notify CMS when the program is unable to receive organ offers for 15 days or more, or when no kidney transplants have been performed for 90 days or more.

In the event CMS accreditation of the transplant program or transplant hospital is terminated either voluntarily or involuntarily:

1. All candidates, recipients, and live donors will be notified at least 30 days before accreditation Terminated.
2. MTP will inform patient's on the center's waiting list and provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list; and
3. Inform Medicare beneficiaries on the center's waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center's termination of approval.
4. This notification will be in writing via a trackable method such as secure email, or certified mail/delivery.

Definitions

OPTN Contractor

References

Centers for Medicare and Medicaid Services

Maine Transplant Program Coverage Policy

Organ Procurement and Transplantation Network (OPTN) Policies and By Laws

Ardyce Peters, MS
Director, Kidney Transplant

Date

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