Proposal to Revise OPTN Data Release Policies

Sponsoring Committee: Data Advisory


Public Comment: August 14, 2015 – October 14, 2015

Effective Date: March 1, 2016

Problem Statement

Current OPTN policy restricts the release of organ procurement organization (OPO) and transplant hospital-identified data. The OPTN Final Rule (the Final Rule) requires the OPTN to release data in these instances:

- In response to “reasonable requests from the public for data needed for bona fide research or analysis purposes”
- In response to “reasonable requests from the public for data needed to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes.”

The Health Resources and Services Administration (HRSA) clarified that this portion of the Final Rule applies to release of data identified by transplant hospital or OPO, which makes current OPTN policy inconsistent with the Final Rule.

Summary of Changes

The revised policy confirms that the OPTN will release OPTN data according to the Final Rule and other applicable federal and state laws and regulations. The remainder of the data release process will be maintained in standard operating procedures that will be available to the public.

What Members Need to Do

Members will not need to do anything to comply with this policy. Both members and the public will have access to more OPTN data. The process for requesting institution-identified OPTN data will be publicly available in the Standard Operating Procedures for Review of OPTN Data Requests.
Policy 19: Data Release

The OPTN Contractor will release OPTN data according to the Final Rule and other applicable federal and state laws and regulations. The OPTN Contractor will release all OPTN data requested by the Secretary of the Department of Health and Human Services (HHS).

19.1 Mailing Lists

Lists showing members' or program directors' names with addresses or telephone numbers may be released, only if both of the following requirements are met:

1. The Executive Director deems the request to be for a legitimate, non-commercial purpose furthering the objectives of the OPTN.
2. The OPTN Contractor receives an executed agreement restricting the use of the information for the permitted purpose.

19.2 Composite Demographic Data

The OPTN Contractor may release to the public any composite demographic national, regional, or state data that is provided to HRSA through the OPTN Contract, such as the following:

- The number of transplant recipients, according to organ type, ethnicity, blood type, gender, and age
- The number of candidates on the Waiting List according to organ type, ethnicity, blood type, gender, and age
- The number and outcome of organs recovered

19.3 Organ Center Data

The OPTN Contractor may release to the public composite Organ Center information such as the following:

- The number of organs allocated through the Organ Center
- Data reflecting Organ Center activity
- The number and final destination of kidneys placed internationally through the Organ Center

19.4 Sharing Arrangements

The OPTN Contractor may release to the public the names of members participating in sharing arrangements approved by the Board of Directors.

19.5 Members

The OPTN Contractor may release to the public listings of members (including names of personnel).

19.6 Public Release of Transplant Hospital and OPO Activity

The OPTN Contractor may release to the public, without obtaining permission from each member, the analysis results containing the following data:
1. Updated transplant hospital-specific waiting list activity, by organ type, including but not limited to the number of candidates on the waiting list at the initiation of a period; the number of candidates added to the list; and the number of candidates removed from the list for death, transplant, and other reasons and, to the extent relevant to the organ type, the probability of survival on the waiting list within a specific period of time stratified by demographic and medical factors as determined appropriate by the Policy Oversight Committee (POC). These data may be presented on a calendar year basis and for such portions of a calendar year as determined by the POC.

2. Updated transplant hospital-specific waiting list size, by organ type, stratified by demographic and medical factors as determined appropriate by the POC.

3. Updated transplant hospital-specific or OPO-specific waiting time information, by organ type, stratified by demographic and medical variables as determined appropriate by the POC, and the probability of receiving a transplant within a specific period of time stratified by demographic and medical factors as determined appropriate by the POC.

4. Updated transplant hospital-specific risk adjusted survival rate information, along with percentage of transplants with follow up information, using data that may be validated by the member through the OPTN Contractor, by organ type, assessing transplants performed during a period that allows the OPTN Contractor sufficient time to collect the data and compute the rates as determined by the POC. The adjusted, transplant hospital-specific survival rate information may include, to the extent relevant to the organ type, the probability of survival pre-transplant, post-transplant and the probability of survival with or without a transplant. An appropriate period of analysis also will be determined by the POC.

5. Updated transplant hospital-validated transplant volumes as may be validated by the member through the OPTN Contractor, by organ type, stratified by demographic and medical factors as determined appropriate by the POC. These data may be presented on a calendar year basis and for such portions of the calendar year as determined by the POC. At a minimum, the OPTN Contractor may release the following transplant hospital volume information:

- Transplant hospital-specific transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, for recipients of a particular age.
- Transplant hospital-specific transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, for recipients with a particular diagnosis.
- Transplant hospital-specific transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, by deceased and living donor transplant.
- Transplant hospital-specific multi-organ transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor.
- Transplant hospital-specific non-resident alien transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, by deceased and living donor transplant.
- Transplant hospital-specific waiting list size on any given day, by organ type, according to the waiting list.
- OPO-specific data on the number of non-U.S. citizen organ donors, by year and by organ type, using data that may be validated by the members through the OPTN Contractor.
- Transplant hospital- and OPO-specific data submission compliance rates.
- Updated OPO-specific donor procurement volumes, using data validated by the member through the OPTN Contractor, including organ-specific authorization, procurement, and utilization volumes, by OPO; and numbers of donors by OPO, using data validated by the member through the OPTN Contractor, stratified by demographic and medical factors for such period(s) as determined appropriate by the POC.
- Updated OPO-specific organ transplant volume, using data validated by the member through the OPTN Contractor, showing number of organs procured, number of organs imported into the OPO, and number of organs exported from the OPO. These data may be presented on a calendar year basis and for such portions of a calendar year as determined by the POC.
OPTN/UNOS Policy Notice

- OPO-specific organ transplant volume and size of waiting list, using data validated by the member through the OPTN Contractor, by organ type, stratified by demographic and medical factors for such period(s) as determined appropriate by the POC.
- Transplant hospital, OPO, or other organization-specific data as approved by the Executive Committee, which the OPTN anticipates will be otherwise duly released by the Department of Health and Human Services (HHS) to the public, together with such explanatory or other text or material as the Executive Committee deems appropriate to assist readers in understanding the data.

19.7 Release of Transplant Hospital Specific Data

The OPTN Contractor may release to OPO members such transplant hospital specific data as are required for the OPOs to prepare reports or other documents required by the OPTN for the purposes of assessing the impact of variances, alternative local units and sharing agreements on organ allocation.

19.8 Review of Member Specific Data

During the data validation process, the OPTN Contractor may release to members for their review such primary data as may be needed for member-specific reports for public release. For example, donor and histocompatibility data about transplants performed at a transplant hospital may be sent to that transplant hospital for review (but not for modification without instruction to the OPTN Contractor by the original institution submitters). Conversely, for these purposes, laboratories and OPOs may receive relevant data submitted to the OPTN Contractor by transplant hospitals. The members that receive the data will not publish or publicly disseminate outcomes of specific recipients, physicians, or institutions.

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?
  - 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
19.10 Information Brought before the Board of Directors

The OPTN Contractor may release to the public any information brought before the Board of Directors in public sessions.

19.11 Release of Human Leukocyte Antigen (HLA) Type of a Recipient’s Prior Donor

The OPTN Contractor may release a recipient’s prior donor’s HLA type to a transplant hospital if the recipient is under that transplant hospital’s care, or to the laboratory that provides services to that transplant hospital, without obtaining permission from the transplant hospital that performed the original transplant or the laboratory that performed the donor’s typing.

19.12 Release of HLA Type of Donors and Recipients with Laboratory Name and Identifier

The OPTN Contractor may release, without obtaining permission from each member laboratory, the HLA type of deceased donors and recipients with the name and identifier of the laboratory that performed the typing to member laboratories for the purpose of resolving discrepant donor and recipient HLA typing results as set out in Policy 4.4: Resolving Discrepant Donor and Recipient HLA Typing Results.

19.13 Access to Database

Only OPTN Contractor staff, or individuals engaged by or adjunct to Contractor staff who are bound by contracts that prohibit competing interests and breaches of confidentiality, will be permitted to program or have direct access to data within the OPTN computer match program, or waiting list, or maintained in any other form. Members requesting access to data regarding their own candidates and recipients will be provided access to that information when practicable as determined by the OPTN Project Director. Unless permitted elsewhere in policy, neither individuals nor members will be given access to individual candidate, recipient, or member-specific information other than that from their own organization, without prior written approval from those individuals or members identified. Candidate, recipient, and institution-identified data will be made available to the Scientific Registry for Transplant Recipients (SRTR) Contractor.

19.14 Transfer of Information

All requests for data should be made through the Data Request System. Requests involving twenty hours or more of programming time or any statistical analyses that are considered to be extensive may be subject to the additional requirements in Policy 19.15: Specific Projects.

Unless permitted by this Policy, data will be provided with the deletion of all candidate, recipient and transplant hospital specific identifying information. Comprehensive datasets with transplant hospital and candidate and recipient identifying information encrypted may be given out for research purposes with the approval of the POC.

Under some circumstances, transplant hospital-specific data (standard analysis files) not otherwise releasable may be provided to bona fide researchers, subject to the approval of the POC using as guidance the Agreement for Release of Data, as approved by the POC. In order to
obtain these data, the submitting individual must meet the conditions for their release and sign an Agreement for Release of Data, which sets forth confidentiality and security stipulations for the data's release and use. Such data may be provided on a cost reimbursement basis.

Use of such data must meet the requirements of Policy 19.16: Public Use, Presentations, and Publications.

As required by the OPTN contract, the OPTN Contractor may release records which are identifiable as to candidate, recipient, transplant hospital or OPO without a signed Agreement for Release of Data only pursuant to official requests for data from the Department of Health and Human Services in accordance with federal or state laws and regulations.

19.15 Specific Projects

Any individual or group requesting data requiring twenty or more hours of programming time and/or any statistical analysis of a specific question by the OPTN Contractor staff may be asked to submit a written concept paper to the POC. The POC (its chair plus representative committee members) will vote to approve or disapprove each request, and may also prioritize approved requests, based on scientific or clinical merit, importance to the OPTN, and the potential ability to address the question. The approval and priority status of each request will be provided to the submitting individual. Upon approval, the submitting individual will be notified of the OPTN Contractor staff assigned to complete the request. The submitting individual must indicate to the assigned staff whether he/she wishes to be directly involved in the analysis and the project work group.

Data will be provided with the deletion of all candidate and recipient specific identifying information. Transplant hospital identifiers may be provided to bona fide researchers who meet the conditions specified in Agreement for Release of Data, which sets forth confidentiality and security stipulations for the data's release and use. Such data may be provided on a cost reimbursement basis. Use of such data will require written acknowledgment of the source of the data and the date it was provided, as required by Policy 19.16: Public Use, Presentations, and Publications.

19.16 Public Use, Presentations, and Publications

All scientific data provided and/or analyses performed by the OPTN Contractor utilizing data collected for the OPTN must adhere to the following specific requirements regarding approval, content, confidentiality, and authorship.

19.16.A Public Use or Presentation of Specific Projects or Studies

The scientific and analytical content of all abstracts or manuscripts developed from customized data requests, comprehensive encrypted datasets, or standard analysis files must be approved by the POC and any ad hoc work group appointed by that Committee prior to their public presentation or publication. If the analysis has not been provided prior to release by the investigator or institution, the OPTN Contractor cannot assume responsibility for the correctness of the findings or interpretations. Failure to include the OPTN Contractor in pre-release preparation may be an adverse consideration in subsequent applications by the investigator or institution for additional data. Any contractor staff that makes a significant intellectual contribution to a study abstract, presentation, or manuscript should be offered the opportunity to be included as an author. Contractor staff may not be listed as study authors without obtaining written permission from the appropriate staff. A copy of all published abstracts, manuscripts, or news releases should be submitted to staff and/or the POC for informational purposes as soon as practicable.
19.16.B—Data Obtained Through the Data Request System

Abstracts and manuscripts prepared using routinely available data obtained through the data request system do not require approval by the POC. Routinely available data will comprise all of the following:

1. Data provided in regularly updated standard reports
2. Data requested by OPTN members regarding their own institution or candidates and recipients
3. Data requested by the Department of Health and Human Services

However, the source and date of the data obtained must be acknowledged in text or graphic presentations. A copy of each published abstract, manuscript, or news release should be submitted to OPTN Contractor and/or the POC for informational purposes as soon as practicable. Publications that use data collected for the OPTN will include the following notice: The data reported here have been supplied by [XXX], the OPTN Contractor. The interpretation and reporting of these data are the responsibility of the authors and in no way should be seen as an official Policy or interpretation of the OPTN, or the U.S. Government.

19.17 Committee Access to Data

Confidential Information, as herein defined, will not be made available in a public meeting. In a non-public forum or meeting setting, access to Confidential Information will be limited to members of the Board of Directors, members of permanent standing or ad hoc committees, OPTN Contractor staff and individuals engaged as an adjunct to Contractor staff. Access will be limited to the above described individuals, provided that these individuals are performing functions on behalf of the OPTN and are either bound by a fiduciary responsibility to the OPTN or a contractual obligation to the OPTN Contractor to maintain the confidentiality of such data and information. These individuals will have no ownership right in or to any of the Confidential Information and maintenance of the Confidential Information will be a private and confidential matter which is required for the continued success of the OPTN and its business. This Confidential Information includes but is not limited to financial data and information, data and information relating to procedural and substantive needs, problems, developments and projects; and data and information regarding deceased and living organ donors and recipients and institutions involved in organ transplantation, which constitute sensitive medical data or information subject to federal or state confidentiality statutes and regulations, all of which constitute trade secrets or confidential information of the OPTN. All such data and information, together with business practices and procedures of the OPTN will be referred to collectively as "Confidential Information."

At such time as it becomes necessary to present or review candidate and recipient specific or transplant hospital specific data or other Confidential Information, such data or Confidential Information will be provided in individual packets for review at that non-public meeting only. At the conclusion of the meeting all individual packets will be collected by the administrative staff, and no such data or Confidential Information will be permitted outside the meeting room except that maintained by administrative staff and adjunct personnel. When practicable, the Confidential Information will be displayed electronically via overhead projection or slide projection for discussion purposes thereby eliminating the need for individualized sets of the Confidential Information. Only OPTN Contractor staff, or government staff pursuant to contractual requirements, will be able to retain the data or Confidential Information in written or electronic form.

In no event will any person, other than OPTN Contractor staff and adjunct personnel in attendance in any non-public meeting be permitted to have access to these data or confidential information outside the meeting room. Cooperation and compliance with these procedures will
ensure the integrity of the OPTN and foster the trust of those who are associated with or who have dealings with the OPTN.