

Date: May 23, 2019

Request: The Health Resources and Services Administration (HRSA) requests changes to the Organ Procurement and Transplantation Network (OPTN) Information Collection (OMB #0915-0157, expires 07/31/2020).

Purpose: This clarification is necessary to align OPTN information collection from lung transplant programs with corresponding requirements approved by the OPTN Board of Directors.

Time Sensitivity: HRSA would appreciate this change memo being reviewed as soon as possible.

PROPOSED CLARIFICATION

Section 372 of the Public Health Service (PHS) Act (42 USC § 274) requires that the Secretary, by contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN). The OPTN operates and maintains a national waiting list of individuals requiring organ transplants, maintains a computerized system for matching donor organs with transplant candidates on the waiting list, and operates a 24-hour system to facilitate matching organs with individuals included in the list.

The OPTN must assist organ procurement organizations (OPOs) in the distribution of organs equitably among transplant patients nationwide and adopt and use standards of quality for the acquisition and transportation of donated organs. In accordance with Section 372(b)(2)(I) of the PHS Act (42 U.S.C. § 274 (b)(2)(I)), the OPTN must also collect, analyze and publish data concerning organ donation and transplants.

Data for the OPTN data system are collected from transplant hospitals, OPOs, and histocompatibility laboratories. The information is used to: facilitate organ placement and match donor organs with recipients; monitor compliance of member organizations with Federal laws and regulations and with OPTN requirements; review and report periodically to the public on the status of organ donation and transplantation in the United States; provide data to researchers and government agencies to study the scientific and clinical status of organ transplantation; and perform transplantation-related public health surveillance including possible transmission of donor disease.

On June 11-12, 2018, the OPTN Board of Directors (Board) approved changes to one section of the Lung Transplant Recipient Follow-up (TRF) form, which collects follow-up data on the health of lung transplant recipients post-transplant. The OPTN determined that utility of the

current data collection is limited because it does not capture all of the prognosis possibilities for declining lung function and may not accurately describe the type of transplant rejection a patient is exhibiting. “Chronic lung allograft dysfunction” (CLAD) is a broader, more contemporary definition of post-transplant lung dysfunction. The proposed change will modify the lung recipient follow-up form to align with updated professional definitions. Refining the outcomes data the OPTN collects can better inform future policy.

The respondents who will complete the application form include transplant centers that perform lung transplants.

Administrative burden is mitigated by the fact that the new data elements are standard measures obtained during pulmonary function tests (PFT) and readily obtainable to both clinical and non-clinical data coordinators in medical records.

Attachment:

Redline version of current Lung TRF form showing the modified data fields and the data fields to be deleted (see page 3 of the form).