

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 Organ Procurement Organizations (OPO) with the common practice of specific infectious disease monitoring by numerous Organ Procurement Organizations.

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, among other responsibilities, 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 approved a change to the deceased donor registration (DDR) form that collects donor serology data. The purpose of this change is to allow those OPOs who perform the Strongyloides test to be able to report the results. While it is not an OPTN policy requirement to perform donor Strongyloides testing, the addition will make

entering and finding results for this test easily accessible. The new Strongyloides field will mirror the current serology fields by displaying the following options: positive, negative, cannot disclose, not done, indeterminate.

The respondents who will complete the application form are OPOs.

An additional serological result will not pose a significant change in burden since the serological results are generally reported together.

The Strongyloides field will be added to the following form: DDR.

Attachment:

Redline of current DDR showing proposed additional data field (see page 5 of the form).