

- Request:** The Health Resources and Services Administration (HRSA) requests changes to the Organ Procurement and Transplantation Network (OPTN) Information Collection (OMB #0915-0184)
- Purpose:** This clarification is necessary to align elements of OPTN membership application forms with corresponding requirements approved by the OPTN Board of Directors.
- Time Sensitivity:** 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.

In December 2015, the OPTN Board of Directors (Board) approved new bylaws pertaining to pediatric transplant membership requirements, with the stipulation that the pediatric bylaws would not be implemented until after December 2018. The purpose of the new bylaws is to ensure that a transplant program must have an approved pediatric component in order to perform transplants in patients less than 18 years old. To be approved for a pediatric component, a

program must identify a qualified primary pediatric surgeon and a qualified primary pediatric physician to serve as key personnel.

The respondents who will complete the application form are transplant programs that have had at least one pediatric patient on its waiting list in the last five years.

The burden on members related to the revisions will be neutral to approximately 10 minutes depending on whether the program is proposing a separate pediatric primary surgeon and/or physician. Some sections of the forms have been streamlined to reduce the amount of time necessary to complete the forms.

Attachment:

Redline versions of current membership application forms showing the modified data fields.