

# Summary of Changes

## OPTN Application Forms

### (OMB No. 0915-0184)

The forms have been revised in order to make the terminology and format more consistent between the different applications, especially those that are organ specific. Notable changes include:

- The forms have been modified to use the language and terms that are consistent in the plain language rewrite of the OPTN Bylaws and policies.
- Sections, such as the laboratory applications reflect extensive revisions to the bylaws.
- Questions that might not have been receiving the expected types of responses have been slightly modified to add clarity.
- Questions have been rearranged in the forms and renumbered for improved flow.
- Instructions have been removed from the OMB forms and to allow for more real time editing based on feedback from respondents.

In addition to the formatting improvements, there are several notable changes to specific forms:

#### **Organ Specific Application – General Section**

Part 1:

- **Section A:** table reformatted.
- **Section B:** table reformatted, changed cardiac to circulatory (DCD definition).

Part 2:

#### **Organ Specific Applications:**

- **Section A:** table reformatted; removed heart/lung; removed questions not relevant to new programs or that were captured elsewhere in the application (CMS notification of change in personnel, LD recoveries).
- **Section B:** table reformatted.
- **Section C:** tables combined for various personnel, removed check lists that were bylaw specific and not required. Questions relating to anesthesiology director were removed, as they are covered in the organ specific sections of the application and redundant.
- **Section D:** reformatted response space and clarified questions; added questions relating to QAPI, and comprehensive transplant service.
- **Section E:** tables reformatted; questions reworded.
- **Section F:** removal of unnecessary information.
- **Section G:** Removed a question; reformatted response space and clarified questions.
- **Section H:** Histocompatibility testing arrangements added to this part of the application in place of only having this information in Part A of the OPO application. Lab section moved from lab module.

#### **Overall Changes:**

- Removed detailed questions about the experience and training for additional surgeons and physicians.
- Removed request for information about “other” surgeons and physicians.
- Combined tables for experience and training for surgeons and physicians.

- Due to major format changes much of the language was stricken and then retyped even though the actual text did not change. It was easier to show it this way.

Kidney: See overall changes. Additionally, living donor recovery were extracted and placed in a new section.

Liver: See overall changes. Additionally, living donor recovery were extracted and placed in a new section.

Pancreas: See overall changes.

Heart: See overall changes.

Lung: See overall changes.

Pancreas Islet: Form restructured. Surgeon & Physician questions incorporated in Pancreas Program application. Remaining questions in this section pertain only to Pancreas Islet transplant programs. Burden was reduced because less supporting documentation is requested from the supporting team members.

### **OPO Applications**

- The previously separate applications for hospital-based and independent OPOs have been merged into a single form with a check off box for the application type.
- Other changes include a rearrangement of questions for better flow and organization. Questions have been made more consistent between the two types of applications.
- Bylaw changes resulted in addition of a few questions, including interim periods for executive and medical director appointments, medical director licensure, process for maintaining confidentiality of donors, how OPO will address multi-cultural and diversity issues.
- New questions added for description of QAPI process, patient safety contact and process, and how the OPO will ensure compliance with OPTN obligations.

### **Histocompatibility Laboratory Application**

- The previously approved applications for hospital-based and independent histocompatibility laboratories have been merged into a single form with a check off box for the application type.
- The placement of instructional items and some questions has changed in order to improve the format and make the forms more intuitive for the applicant.
- The majority of the changes in the form have been made in order to reflect the changes in the bylaws and the types of information that needs to be collected the OPTN to make a determination to designate a laboratory as approved.
- The ASHI related instructions have been removed from the document and bylaws have been reference for details.
- New questions added for description of QAPI process, patient safety contact and process, and how the OPO will ensure compliance with OPTN obligations.

### **Other Applications**

The applications listed below were amended to reflect amendments in bylaw language as well as reformatted.

- Medical/ Scientific Member
- Public Organization
- Business Member
- Individual Member

### **New Forms**

- **Change in Key Personnel Application - Histocompatibility Laboratory Membership.**

This form was created in order to standardize the data collection tool when there is a change in primary laboratory director, technical supervisor, or clinical consultant and to have the authority of an OMB approved form. This information was been collected through a letter of request and by sharing information with ASHI & CAP. Neither of these agencies has a similar form so a standardized form was necessary. The questions in the application are adapted from the new lab application form. Having the form approved by OMB will give the OPTN greater authority.

- **Application for Approval of Change in Key Personnel Organ Procurement Organization Procurement Organization (OPO)**

This form was created in order to standardize the data collection tool when there is a change in primary laboratory administrative or medical director and to have the authority of an OMB approved form. This information was been collected through a letter of request. The questions in the application are adapted from the new OPO application form.