

## **High Level Summary of Revisions to OPTN Membership Application forms (0915-0184)**

HRSA is submitting this summary of revisions to forms in the OPTN Membership Application ICR package (0915-0184) rather than submitting individual redlines of forms. The revisions are proposed to make OPTN membership application requirements more clear and organized, and thus less cumbersome for applicants to complete. Proposed revisions include changes to wording to make questions more consistent with the language of the OPTN Bylaws (Bylaws). The Bylaws outline membership requirements for organizations and individuals to participate in the U.S. transplant network. In addition, the applications have been revised so that the sequence of questions is parallel to that of the Bylaws so that an applicant can have the application and Bylaws side-by-side for easy reference.

In addition, the 2020 OPTN Membership Application revisions will coincide with the introduction of a web based tool that will assist users to fill out the application forms and submit them electronically. Approval signatures required for application submission will also be captured electronically using a web based application tool.

Given these changes, the overall burden has decreased significantly from an estimated 7,020 total burden hours in 2017 to 4,755 hours in this current proposed revision package, although some forms have been combined into one more comprehensive form resulting in increased burden hours for a particular form.

Other changes include the following:

- The “Membership – Surgeon or Physician transplant log,” previously included in other forms, is now a separate form that will be attached to each application. This new separate form will provide applicants with all requirements for a log per OPTN Bylaws for each organ and pathway.
- Also within the applications, what were formerly known as “checkboxes”—fillable tables that were not really checkboxes at all—were removed and real checkboxes were put in to reduce the burden to applicants. The “narrative” section was replaced by checkbox “attestations,” which will serve the same purpose: understanding relevant and recent surgeon and physician applicant experience. The previous membership applications had several places for the applicants to sign; the new application requests only one signature from each individual member applicant involved.
- Previous application attachments for key personnel and living donor components have been streamlined into one form for each respective organ application.
- Pediatric Bylaw Requirements—where applicable—were also given their own sections in the organ applications.
- The Certificate of Assessment (formerly known as Certificate of Investigation) and the Primary Coverage Plan Checklist were pulled out of the previous organ specific applications and given their own, separate form.
- VCA Transplant program applications, which were previously submitted as separate applications based on the type of VCA body part transplanted, is now one single

application with sections for each VCA organ type.

- Personnel changes for Organ Procurement Organizations (OPOs) and Histocompatibility Laboratories have also been combined with organization applications, so that OPO and lab applicants will be able to use one respective application for new and personnel changes.

The table below provides more detail regarding the difference in the 2017 ICR package and the current 2020 package, and demonstrates which forms have been combined. Again, the overall purpose of these modifications is to make OPTN application requirements more clear and organized, more user-friendly, and less burdensome.

| Current Cycle File HRSA SWIFT File Names:<br>Expiring 7/31/2020 | New HRSA File Names                       | 60 Days FRN Supporting Statement<br>Names and Draft 30 Days FRN           | Notes   |
|---|---|---|---|
| A1_NewTransplantHospital_Cover                                  | Membership_Transplant<br>Hospital_General | OPTN Membership Application for Transplant<br>Hospitals                   |   |
| A2_NewTransplant_General  |   |   |   |
| B1_NewTransplantProgram_Cover_Clean_<br>HRSA                    | N/A                                       | N/A   | No longer needed. Information is captured in new<br>Kidney, Liver, Pancreas, Pancreas Islet, Heart, Lung<br>and Intestine             |
| B3_Kidney_LDKidney  | Membership_Kidney_LDKidney                | OPTN Membership Application for Kidney<br>Transplant Programs             |   |
| B4_Liver_LDLiver  | Membership_Liver_LDLiver                  | OPTN Membership Application for Liver<br>Transplant Programs              |   |
| B5_Pancreas   | Membership_Pancreas                       | OPTN Membership Application for Pancreas<br>Transplant Programs           |   |
| B6_Heart  | Membership_Heart                          | OPTN Membership Application for Heart<br>Transplant Programs              |   |
| B7_Lung   | Membership_Lung                           | OPTN Membership Application for Lung<br>Transplant Programs               |   |
| B8_PancreasIslet  | Membership_PancreasIslet                  | OPTN Membership Application for Islet<br>Transplant Programs              |   |
| B9_NewLiving Donor Recoveries                                   | N/A                                       | N/A   | No longer needed. Information is captured in new<br>Kidney and Liver Applications   |
| C_OPO_New   | Membership_OPO                            | OPTN Membership Application for Organ<br>Procurement Organizations (OPOs) | New Form will serve as new program and key<br>personnel change request  |
| G_OPO_DirectorChange  |   |   |   |
| D_HistoLab_New  | Membership_HistoLab                       | OPTN Membership Application for<br>Histocompatibility Laboratories        | New Form will serve as new program and key<br>personnel change request  |
| F_HistoLab_PersonnelChange                                      |   |   |   |
| E_PersonnelChange_Cover   | N/A                                       | N/A   | No longer needed: Members will use relevant<br>portions of their respective organ applications to<br>apply for a key personnel change |
| H_MedicalScientific   | Membership_MedicalScientific              | OPTN Medical/Scientific Membership<br>Application                         |   |
| I_PublicOrg   | Membership_PublicOrg                      | OPTN Public Organization Membership<br>Application                        |   |

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|---|--|---|---|
| J_Business  | Membership_Business                                      | OPTN Business Membership Application  |   |
| K_Individual  | Membership_Individual                                    | OPTN Individual Membership Application  |   |
| L_Intestine   | Membership_Intestine                                     | OPTN Membership Application for Intestine<br>Transplant Programs                              |   |
| M1_VCA_NewTransplantProgram                                     | Membership_VCA   | OPTN Membership Application for Vascularized<br>Composite Allograft (VCA) Transplant Programs | All requests for VCA have been combined into one<br>form  |
| M2_VCA_AW_Intestine   |  |   |   |
| M3_VCA_AW_Kidney  |  |   |   |
| M4_VCA_AW_Liver   |  |   |   |
| M5_VCA_AW_Pancreas  |  |   |   |
| M6_VCA_Head and Neck  |  |   |   |
| M7_VCA_Upper Limb   |  |   |   |
| N1_VCA_Other_NewTransplantProgram                               |  |   |   |
| N2_VCA_Other_PersonnelChange_Cover                              |  |   |   |
| N3_VCA_Other  |  |   |   |
| O_VCA_PersonnelChange_Cover                                     |  |   |   |
|   | Membership_SurgeonOrPhysicianLog                         | OPTN Membership Application Surgeon or<br>Physician Log                                       | New Independent Form. Information was<br>previously collected within organ application. This<br>form will accompany every application and must be<br>filled out as part of membership application |
|   | Membership_CertificateAssessment_<br>ProgramCoveragePlan | OPTN Certificate of Assessment and Program<br>Coverage Plan Membership Application            | New Independent Form. Information was<br>previously collected within organ application. This<br>form will accompany every application and must be<br>filled out as part of membership application |
|   | Membership_Representative                                | OPTN Representative Form  | New Form. Information is routinely collected from<br>member   |
| <b>Total Forms = 30</b>   | <b>Total Forms = 18</b>                                  |   |   |

