OPTN Member Evaluation Plan Preview

The OPTN Member Evaluation Plan will be updated on March 1, 2021, and June 1, 2021, when OPTN policy changes are implemented as part of the alignment of OPTN policies with the 2020 *U.S. Public Health Service Guideline* for assessing solid organ donors and monitoring transplant recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus infection. This preview of Evaluation Plan changes is provided as a planning resource until the Evaluation Plan is updated. All information contained in this document may be subject to future changes.

Policy 2.2: OPO Responsibilities

*Effective Date: 3/1/2021*

**At OPOs, site surveyors will:**

Review a sample of deceased donor records for the following documentation:
- An authorization to donate
- Reasons for excluding any donors from the eligible death definition
- Declaration of death note, including:
  - Date and time of pronouncement of death
  - Signature(s) of the person(s) required under the relevant state's laws
- Blood specimen collection and storage noted in the donor chart, including a collection date that is no earlier than 1 day before the donor recovery date

Review a sample of deceased donors in UNet℠ to verify that the following source documents were uploaded to UNet℠:
- ABO typing
- ABO subtyping (if applicable)
- Results for infectious disease tests that are required by *Policy 2.9: Required Deceased Donor Infectious Disease Testing*
- Death pronouncement
- Authorization for donation
- HLA typing

Review a sample of deceased donor records to verify that data reported through UNet℠ is consistent with source documentation, including:
- Infectious disease test results

**OPOs will provide:**

The requested sample of deceased donor medical records

**What is changing?**

Surveyors will begin verifying that documentation of donor blood specimen collection and storage includes a collection date that is no earlier than 1 day prior to the donor’s recovery date.
Policy 2.4: Deceased Donor Medical and Behavioral History

Effective Date: 3/1/2021

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- The donor was assessed for the risk of acute HIV, hepatitis B (HBV), and hepatitis C (HCV) infection according to the criteria in the U.S. Public Health Service (PHS) Guideline
- Whether or not the OPO’s assessment of the donor according to the U.S. PHS Guideline identified any risk of acute HIV, HBV, or HCV infection
  - If the OPO identified a risk of acute HIV, HBV, or HCV infection in the donor, that the OPO communicated this information to all receiving transplant programs
- Any evidence in the medical and behavioral history that the donor was exposed to or received HPDGH
  - If the donor was exposed to or received HPDGH, that this was communicated to the receiving transplant programs

OPOs will provide:

The requested sample of deceased donor medical records

What is changing?

Surveyors will begin verifying that OPOs are assessing donors using the risk criteria in the 2020 U.S. PHS Guideline.

Policy 2.5: Hemodilution Assessment

Effective Date: 3/1/2021

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- The calculations used to assess hemodilution
- The date and time of the blood draw for the blood used for the screening tests
- The date and time of the blood draw used to determine hemodilution
- If the donor specimens are hemodiluted, that the following were communicated to the accepting transplant programs:
  - Any screening results from the hemodiluted specimens
  - The tests completed on the hemodiluted specimens
  - The hemodilution calculation used for the hemodiluted specimens, if requested

OPOs will provide:

The requested sample of deceased donor medical records

What is changing?

Surveyors will no longer verify that a donor is reported as meeting U.S. PHS Guideline risk criteria solely because hemodiluted specimens were used for donor screening tests, since hemodilution has been removed from the list of risk criteria in the 2020 U.S. PHS Guideline.
Policy 2.9: Required Deceased Donor Infectious Disease Testing

Effective Date: 3/1/2021

At OPOs, site surveyors will:

Review a sample of deceased donor records for documentation of results or other evidence that the following were performed and that results reported through UNet™ are consistent with source documentation:

- Blood and urine cultures
- HIV, HBV, and HCV testing using samples drawn no earlier than 4 days before the donor recovery date:
  - HIV antibody (anti-HIV) donor screening test or HIV antigen/antibody (Ag/Ab) combination test
  - HIV ribonucleic acid (RNA) screening or diagnostic nucleic acid test (NAT)
  - Hepatitis B surface antigen (HBsAg) screening test
  - Hepatitis B core antibody (total anti-HBc) screening test
  - Hepatitis B deoxyribonucleic acid (DNA) screening or diagnostic NAT
  - Hepatitis C antibody screening test (anti-HCV)
  - Hepatitis C RNA screening or diagnostic NAT
- Cytomegalovirus (CMV) antibody (anti-CMV) screening or diagnostic test
- Epstein-Barr Virus (EBV) antibody (anti-EBV) screening or diagnostic test
- Syphilis screening or diagnostic test
- Toxoplasma Immunoglobulin (IgG) antibody test

OPOs will provide:

The requested sample of deceased donor medical records

What is changing?

Surveyors will begin verifying that OPOs are performing HIV RNA and HBV DNA nucleic acid tests on deceased donors. Surveyors will also begin verifying that samples used for all required HIV, HBV, and HCV testing were drawn no earlier than 4 days before the donor recovery date.


Effective Date: 3/1/2021

At living donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the donor psychosocial evaluation was completed and addressed the following:

- Psychosocial issues that might complicate the living donor's recovery
- Risks for poor psychosocial outcome
- An assessment of risk criteria for acute HIV, HBV, or HCV infection according to the U.S. Public Health Service (PHS) Guideline
- The living donor's history of smoking, alcohol, and drug use, including past or present substance use disorder
- Factors that warrant educational or therapeutic intervention prior to the final donation decision
• The living donor's understanding of the short and long-term medical and psychosocial risks for both the living donor and recipient
• Whether the decision to donate is free of inducement, coercion, and other undue pressure
• The living donor's ability to make an informed decision
• The living donor's ability to cope with the major surgery and related stress
• Whether the donor has a realistic plan for donation and recovery, with social, emotional and financial support available as recommended
• The living donor's occupation, employment status, health insurance status, living arrangements, and social support
• The living donor's understanding of the potential financial implications of living donation

Interview relevant staff, and substantiate the information obtained in the interview through review of internal policies, procedures and protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference to obtain evidence that the hospital's standard practice is:
• That the person performing psychosocial evaluations of living donors is someone with the role/title of psychiatrist, psychologist, masters-prepared social worker, or licensed clinical social worker

Recovery hospitals will provide:
The requested sample of living donor records
The recovery hospital's internal policies, procedures and protocols for the care of living donors
Evidence as needed to verify compliance
Access to relevant staff who can answer interview questions

What is changing?
Surveyors will begin verifying that living donor recovery hospitals are assessing potential living donors using the risk criteria in the 2020 U.S. PHS Guideline.

Policy 14.3: Informed Consent Requirements

Effective Date: 6/1/2021

At living donor recovery hospitals, site surveyors will:
Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for a document signed by the living donor confirming that the donor:
• Is willing to donate
• Is free from inducement or coercion
• Has been informed that he/she may decline to donate at any time

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that:
• The living donor was offered an opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential
• An ILDA was available to assist the living donor during the consent process
Interview relevant staff, and substantiate the information obtained in the interview through review of internal policies, procedures and protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference to obtain evidence that the hospital’s standard practice is:

- To provide information to living donors in a language in which the donor is able to engage in a meaningful dialogue with the recovery program staff

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital disclosed the following to the living donor:

- It is a federal crime for any person to knowingly acquire, obtain, or otherwise transfer any human organ for anything of value including, but not limited to, cash, property, and vacations
- That the hospital must (or will) provide an ILDA
- Alternate procedures or courses of treatment for the recipient, including deceased donor transplantation
- A deceased donor organ might become available for the recipient before the donor evaluation is completed or the living donor transplant occurs
- Transplant hospitals determine candidacy for transplantation based on existing hospital-specific guidelines or practices and clinical judgment
- The recovery hospital will take all reasonable precautions to provide confidentiality for the living donor and the recipient
- Any transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications, and mortality) that:
  - Exceed local or national averages
  - Do not necessarily prohibit transplantation
  - Are not disclosed to the living donor
- The recovery hospital can disclose to the living donor certain information about candidates only with the permission of the candidate, including:
  - The reasons for a transplant candidate’s increased likelihood of adverse outcomes
  - Personal health information collected during the transplant candidate’s evaluation, which is confidential and protected under privacy law
- Health information obtained during the living donor evaluation is subject to the same regulations as all medical records and could reveal conditions that must be reported to local, state or federal public health authorities
- The recovery hospital is required to report living donor follow-up information at six months, one year, and two years post-donation
- The recovery hospital is required to obtain and store a living donor blood specimen for ten years, only to be used for investigation of potential donor-derived disease
- Any infectious disease or malignancy pertinent to acute recipient care discovered during the first two years of the donor's post-operative follow-up care:
  - May need to be reported to local, state or federal public health authorities
  - Will be disclosed to their recipient’s transplant hospital
  - Will be reported through the OPTN Improving Patient Safety Portal
- The living donor will receive a medical evaluation
- The living donor will receive a psychosocial evaluation
- The hospital may refuse the living donor
• The following are inherent risks associated with evaluation for living donation:
  o Allergic reactions to contrast
  o Discovery of reportable infections
  o Discovery of serious medical conditions
  o Discovery of adverse genetic findings
  o Discovery of abnormalities that may require additional testing at the donor's expense or create the need for unexpected decisions by the transplant team

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided information or disclosure to the donor addressing the risk of the following:
• Death
• Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure
• Abdominal symptoms such as bloating, nausea, and bowel obstruction
• The morbidity and mortality of the living donor may be impacted by age, obesity, hypertension, or other donor-specific pre-existing conditions
• Problems with body image
• Post-surgery depression or anxiety
• Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the recipient dies
• Changes to the living donor's lifestyle from donation
• Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed
• Need for life-long follow-up at the living donor's expense
• Loss of employment or income
• Negative impact on the ability to obtain future employment
• Negative impact on the ability to obtain, maintain, or afford health, disability, and life insurance
• Future health problems experienced by living donors following donation may not be covered by the recipient's insurance
• Risks may be temporary or permanent
• Risks may include those listed, but are not limited to those listed

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided the following information to the living donor regarding recipient outcome and survival data:
• When the recipient transplant hospital is known or is the same as the recovery hospital:
  o SRTR's national 1-year patient and transplanted organ survival rates for the organ being donated
  o SRTR's most recent hospital-specific 1-year patient and transplanted organ survival rates for the recipient's transplant hospital for the organ being donated
• When the recipient transplant hospital is not known:
  o SRTR's national 1-year patient and transplanted organ survival rates for the organ being donated
Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided additional information or disclosure specific to the living kidney donor regarding:

- **Education about expected post-donation kidney function and the potential impact on chronic kidney disease (CKD) and end-stage renal disease (ESRD) on the living kidney donor in the future, including:**
  - On average, donors will have a 25-35% permanent loss of kidney function after donation
  - Although risk of ESRD for living kidney donors does not exceed that of members of the general population with the same demographic profile, risk of ESRD for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors
  - Living donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occurs, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young donor cannot predict lifetime risk of CKD or ESRD
  - Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney
  - The development of CKD and subsequent progression to ESRD may be faster with only one kidney
  - Dialysis is required if the living donor develops ESRD
  - Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to OPTN policy

- **Potential surgical risks:**
  - Decreased kidney function
  - Acute kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period
  - Risks may be temporary or permanent
  - Risks may include those listed, but are not limited to those listed

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided additional disclosure to female living kidney donors that:

- **Risks of preeclampsia or gestational hypertension may be increased in pregnancies after donation**

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided additional information or disclosure specific to the living liver donor regarding:

- **Potential surgical risks:**
  - Acute liver failure with need for liver transplant
  - Transient liver dysfunction with recovery
  - Risk of red cell transfusions or other blood product transfusions
  - Biliary complications, including leak or stricture, that may require additional intervention
  - Post-donation laboratory tests may result in abnormal or false positive results that may trigger additional tests that have associated risks
  - Risks may be temporary or permanent
  - Risks may include those listed, but are not limited to those listed
Recovery hospitals will provide:
The requested sample of living donor records
The recovery hospital’s internal policies, procedures and protocols for the care of living donors
Evidence as needed to verify compliance
Access to relevant staff who can answer interview questions

What is changing?
Surveyors will begin verifying that living donor recovery hospitals are disclosing to living donors that the hospital is required to obtain and store a living donor blood sample for ten years, only to be used for investigation of potential donor-derived disease.

Policy 14.4.A: Living Donor Medical Evaluation Requirements

Effective Date: 3/1/2021

At living donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the donor medical evaluation was completed.

Interview relevant staff, and substantiate the information obtained in the interview through review of internal policies, procedures and protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference to obtain evidence that the hospital's standard practice is:

- That the medical evaluation of the living donor performed at the recovery hospital is reviewed by a physician or surgeon

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that an evaluation of the donor included assessment of:

- Personal history of:
  - Hypertension
  - Diabetes
  - Lung disease
  - Heart disease
  - Gastrointestinal disease
  - Autoimmune disease
  - Neurologic disease
  - Genitourinary disease
  - Hematologic disorders
  - Bleeding or clotting disorders
  - Cancer, including melanoma

- History of infections
- The donor’s active and past medications
- The donor’s allergies
- Coronary artery disease
- Whether the donor has a family history of:
  - Coronary artery disease
  - Cancer
- Occupation
- Employment status
- Health insurance status
- Living arrangements
- Social support
- Smoking, alcohol and drug use/abuse
- Psychiatric illness
- Depression
- Suicide attempts
- Risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. Public Health Service (PHS) Guideline*

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that there are results for:

- Height
- Weight
- BMI
- Vital signs
- A review of major organ systems
- Complete Blood Count (CBC) with platelet count
- Blood type (and subtype if tested)
- Prothrombin Time (PT) or International Normalized Ratio (INR)
- Partial Thromboplastin Time (PTT)
- Metabolic testing, including:
  - Electrolytes
  - BUN
  - Creatinine
  - Transaminase levels
  - Albumin
  - Calcium
  - Phosphorus
  - Alkaline phosphatase
  - Bilirubin
- HCG quantitative pregnancy test (for premenopausal women without surgical sterilization)
- Chest X-ray
- Electrocardiogram (ECG)
- CMV (Cytomegalovirus) antibody testing
- EBV (Epstein Barr Virus) antibody testing
- Syphilis testing
- HIV, hepatitis B (HBV), and hepatitis C (HCV) testing performed no earlier than 28 days before the organ recovery date:
  - HIV antibody (anti-HIV) test or HIV antigen/antibody (Ag/Ab) combination test
  - HIV ribonucleic acid (RNA) nucleic acid test (NAT)
  - Hepatitis B surface antigen (HBsAg) test
  - Hepatitis B core antibody (total anti-HBc) test
  - HBV deoxyribonucleic acid (DNA) NAT
  - Hepatitis C antibody (anti-HCV) test
  - HCV RNA NAT
Review the hospital’s internal policies, procedures and protocols to verify that the hospital has developed and implemented written protocols that address:

- Identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease
- Cancer screening for:
  - Cervical cancer
  - Breast cancer
  - Prostate cancer
  - Colon cancer
  - Lung cancer

Recovery hospitals will provide:

The requested sample of living donor records
The recovery hospital’s internal policies, procedures and protocols for the care of living donors
Evidence as needed to verify compliance
Access to relevant staff who can answer interview questions

What is changing?

Surveyors will begin verifying that living donor recovery hospitals are assessing potential living donors using the risk criteria in the 2020 U.S. PHS Guideline. Surveyors will also begin verifying that living donor recovery hospitals are performing HIV RNA and HBV DNA nucleic acid tests on living donors no earlier than 28 days before the organ recovery date.

Policy 14.8.B Living Donor Specimen Collection and Storage

Effective Date: 6/1/2021

At living donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records for the following documentation:

- Blood specimen collection and storage noted in the medical record
- A collection date for stored blood specimens that is no earlier than 1 day before the donor recovery date

Recovery hospitals will provide:

The requested sample of living donor records

What is changing?

Surveyors will begin monitoring this policy as described above.
Policy 15.2 Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements

Effective Date: 3/1/2021

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that there are results for:

- HIV, hepatitis B (HBV), and hepatitis C (HCV) tests, using blood samples collected during hospital admission for transplant and prior to first anastomosis:
  - HIV, using a CDC-recommended laboratory testing algorithm
  - Hepatitis B surface antigen (HBsAg)
  - Hepatitis B core antibody (total anti-HBc)
  - Hepatitis B surface antibody (HBsAb)
  - Hepatitis C antibody (anti-HCV)
  - Hepatitis C ribonucleic acid (RNA) nucleic acid test (NAT)

- HIV, HBV, or HCV tests demonstrating that the candidate was already known to be infected with HIV, HBV, or HCV, if testing for one or more of these infections was not completed during hospital admission for transplant and prior to first anastomosis.

Transplant hospitals will provide:

The requested sample of medical records.

What is changing?

Surveyors will begin monitoring this policy as described above.

Policy 15.3.B: Donors with Risk Identified Pre-Transplant

Effective Date: 3/1/2021

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- The intended recipient or recipient’s agent gave consent after the organ offer but before transplant when:
  - The accepted organ was from a donor who tested positive for:
    - Hepatitis B surface antigen (HBsAg)
    - Hepatitis B (HBV) nucleic acid test (NAT)
    - Hepatitis C (HCV) NAT
  - The accepted kidney or liver was from an HIV positive donor, and the transplant hospital participates in an approved variance according to Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors.

- The intended recipient or intended recipient’s agent was informed after the organ offer but before transplant that risk criteria for acute HIV, HBV, or HCV infection were present in the donor, when the accepted organ was from a donor with any risk criteria according to the U.S. Public Health Service (PHS) Guideline.
Transplant hospitals will provide:
The requested sample of medical records

What is changing?
Surveyors will verify that the transplant program informed the intended recipient or intended recipient’s agent after the organ offer but before transplant that risk criteria for acute HIV, HBV, or HCV infection were present in a donor whose organ was accepted for that recipient, when any risk criteria according to the 2020 U.S. PHS Guideline were identified in the donor. Surveyors will no longer verify that the transplant program documented specific informed consent from the intended recipient or intended recipient’s agent for organs accepted from donors with risk criteria identified according to the 2020 U.S. PHS Guideline or from donors whose HIV, HBV, or HCV screening was performed using a hemodiluted specimen.

Policy 15.3.C: Required Post-Transplant Infectious Disease Testing
Effective Date: 3/1/2021

At transplant hospitals, site surveyors will:
Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that there are results for:

- HIV, hepatitis B (HBV), and hepatitis C (HCV) tests performed between 28 and 56 days after the date of transplant:
  - HIV ribonucleic acid (RNA) nucleic acid test (NAT)
  - HBV deoxyribonucleic acid (DNA) NAT
  - HCV RNA NAT
- HIV, HBV, or HCV tests demonstrating that the recipient was already known to be infected with HIV, HBV, or HCV, if testing for one or more of these infections was not performed between 28 and 56 days after the date of transplant

Transplant hospitals will provide:
The requested sample of medical records

What is changing?
Surveyors will begin verifying that recipients are tested for HIV, HBV, and HCV via nucleic acid test (NAT) between 28 and 56 days after the date of transplant. Surveyors will no longer verify that the hospital has a written protocol for post-transplant HIV, HBV, and HCV testing of recipients of organs from donors designated as “increased risk” based on the 2013 U.S. PHS Guideline criteria.