

# Impact Summaries

OPTN/UNOS BOARD OF DIRECTORS

December 5-6, 2016

St. Louis, MO

## Table of Contents

1. Components of Each Impact Summary .....	3
2. Level of UNOS Effort and Project Size Categories .....	4
3. Historical OPTN/UNOS Staff Levels of Effort .....	6
4. Current Proposals by Strategic Plan Goals under Board Consideration .....	8
5. Combined Costs for All Proposals .....	10
Proposal Impact Summaries .....	11
Subspecialty Board Certification for Primary Liver and Heart Transplant Physicians .....	11
Updating the OPTN Definition of Transplant Hospital .....	13
Changes to HCC Criteria for Auto Approval .....	15
Modification of the Heart Allocation System .....	17
Ethical Considerations of Imminent Death Donation .....	20
Modifications to Informed Consent Requirements for Potential Living Donors .....	21
Consider Primary Transplant Surgeon Requirement – Primary or First Assistant on Transplant Cases .....	23
Review Existing White Papers for Accuracy and Relevancy .....	25
Updating Primary Kidney Transplant Physician Requirements .....	26

## 1. Components of Each Impact Summary

A proposal **synopsis** summarizes what is described more fully in the committee's report to the Board of Directors (BOD). The document describes who is affected by the proposal and the ways in which it **aligns with OPTN Strategic Goals and the OPTN Final Rule**. A chart appears under each synopsis and includes estimated cost information for both UNOS Staff and OPTN/UNOS Member information.

The remaining portion of the **Impact Summary** estimates the resources that will be required following OPTN/UNOS BOD approval, for both the project's implementation and ongoing effort phases, as described below.

- The **Implementation Effort Estimate** provides UNOS departmental estimates of the staff hours needed for the specific tasks to bring each approved proposal from words on paper to changes in programming code, new education vehicles for the community, and revised compliance reports (as examples). Each hours estimate is multiplied by that department's anticipated 2016-2017 average staff cost per hour (including salary, benefits, and indirect costs) for the total cost estimate shown. The level of effort is from the date of Board approval to the date of full implementation for all UNOS departments.

The implementation effort estimated for OPTN/UNOS members is the estimated additional total cost that might be anticipated if the proposal is implemented. This is a high-level estimate, agreed upon by representative members (Fiscal Impact Advisory Group). The estimates include potential personnel, operating, and capital impact to transplant centers, organ procurement organizations, and labs. The cost impact does not account for billing passed to other entities, such as insurance providers. Because programmatic and billing practices differ among members, it is difficult to assess actual financial burden on individual members. The estimates and analysis are intended to provide Board members and community with more information to anticipate changes in cost due to approval of proposals.

- The **Ongoing Annual Estimate** recognizes that most projects will require ongoing support by UNOS staff following full implementation. Due to the extensive policy interrelations within the computer system, new BOD actions can affect the functionality of existing programming operations. This requires maintenance resources while the additional changes take place. Alternatively, some projects may phase out over time, requiring less or no future support. To calculate the ongoing costs, staff and the Fiscal Impact Advisory Group estimated the total ongoing costs for the three years after implementation. (Three years is the length of time to complete one full site survey cycle following implementation.) The ongoing annual estimate is then calculated as the average costs for the first three years of implementation. Again, programmatic and billing practices may differ among members, so an explanation of possible ongoing costs is provided to consider variables and potential cost burden. The Fiscal Impact Workgroup estimated the additional annual post-implementation cost impact that proposals may have on such budgetary items as staff hours, supplies, record keeping, and transportation.

- The ***Discussion: Project Size/Complexity*** is a narrative overview of the major resources and costs associated with each project that may impact UNOS staff or OPTN/UNOS member organizations. Costs to UNOS staff have been historically estimated, but cost estimates to OPTN/UNOS members, including transplant centers, organ procurement organizations, and histocompatibility labs are now a part of this summary. Variables that may cause future costs to be higher or lower for members are also identified.

Note: Impact Summaries are designed to provide information for Board members to use when considering approval of specific committee proposals. Implementation decisions, such as placement on the schedule of work, will be made at a future time by the Executive Leadership.

## 2. Level of UNOS Effort and Project Size Categories

In 2008, the UNOS Project Management Office (PMO) developed a *Guideline for Identifying Project Size* as a tool to help define the most likely approach for successful implementation of approved projects of varying sizes (see table below). Classification using the *Guideline* is based in part on analysis of historical level of effort (LOE) data using a standard mathematical formula of arriving at the mean, with standard deviations representing incremental segments in project sizes. This method more accurately accounts for the specific OPTN/UNOS environment and typical size range of OPTN programming projects. The snapshot table for each Board proposal indicates the category assigned by the *Guideline* to OPTN projects within a similar size range, based on the proposal's estimated total number of hours required for implementation.

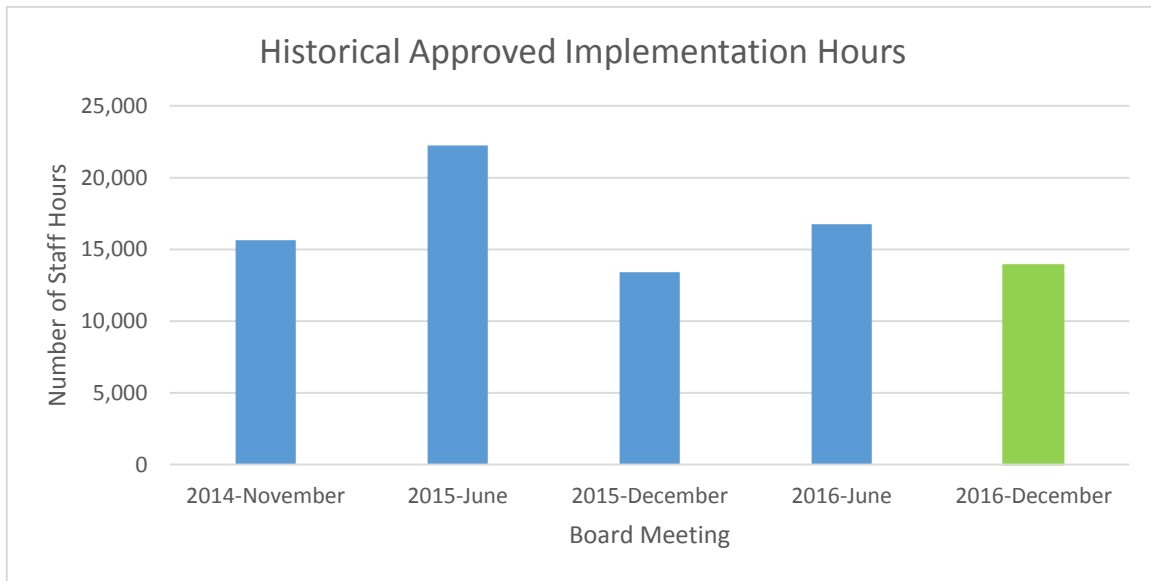
**PMO Guidelines for Identifying Project Size**

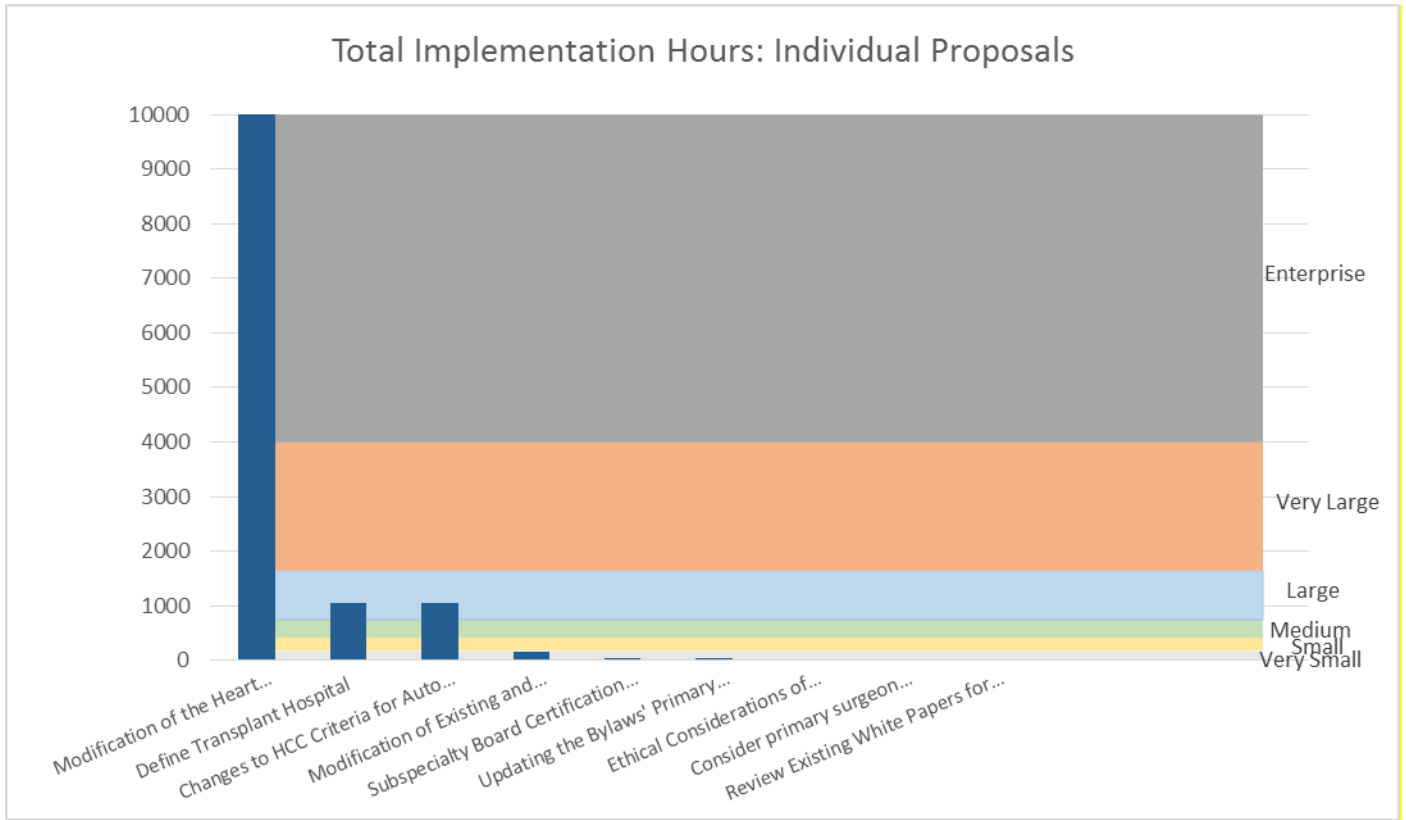
<b>Project Size</b>	<b>Estimated Hours</b>	<b>Historical Examples</b>
Very Small	<180 hrs.	Heart-Lung Allocation Guidance Document (25)
Small	180 - 419 hrs.	Modifications to timeframe for submitting living donor follow-up forms (241)
Medium	420 - 749 hrs.	Pediatric Liver, Remove ICU Requirement (663)
Large	750 - 1649 hrs.	Share 15, Liver (1,150) Share 25, Liver (1,150) Modify Pediatric Liver Hepatoblastoma (1,058)
Very Large	1,650 - 3,999 hrs.	HCC Imaging (1,807) Update CPRA, HLA Frequencies (3,000)
Enterprise	≥4,000 hrs.	Establish KPD (23,400)

### 3. Historical OPTN/UNOS Staff Levels of Effort

To help put this cycle’s portfolio of proposals in perspective, the following chart shows the historical levels of effort of proposals approved by the Board. The average number of implementation hours approved per Board meeting from November 2014 through December 2016 equals 16,388. The average number of programming hours approved per Board meeting is 11,936. Using these averages, IT work typically represents 72.8% of the effort needed to implement proposals. The number of total implementation hours has ranged from a low of 13,420 (December 2015) to a high of 23,685 (June 2015).

For the upcoming December 2016 Board meeting, the estimates are 13,900 hours (all implementation) and 12,460 (IT implementation only). IT hours represent 89.6% of all implementation efforts for this upcoming cycle.





The chart above shows each proposal by total implementation hours. The horizontal bands reflect the PMO project sizes as explained on page 4. Four of the proposals require IT programming hours.

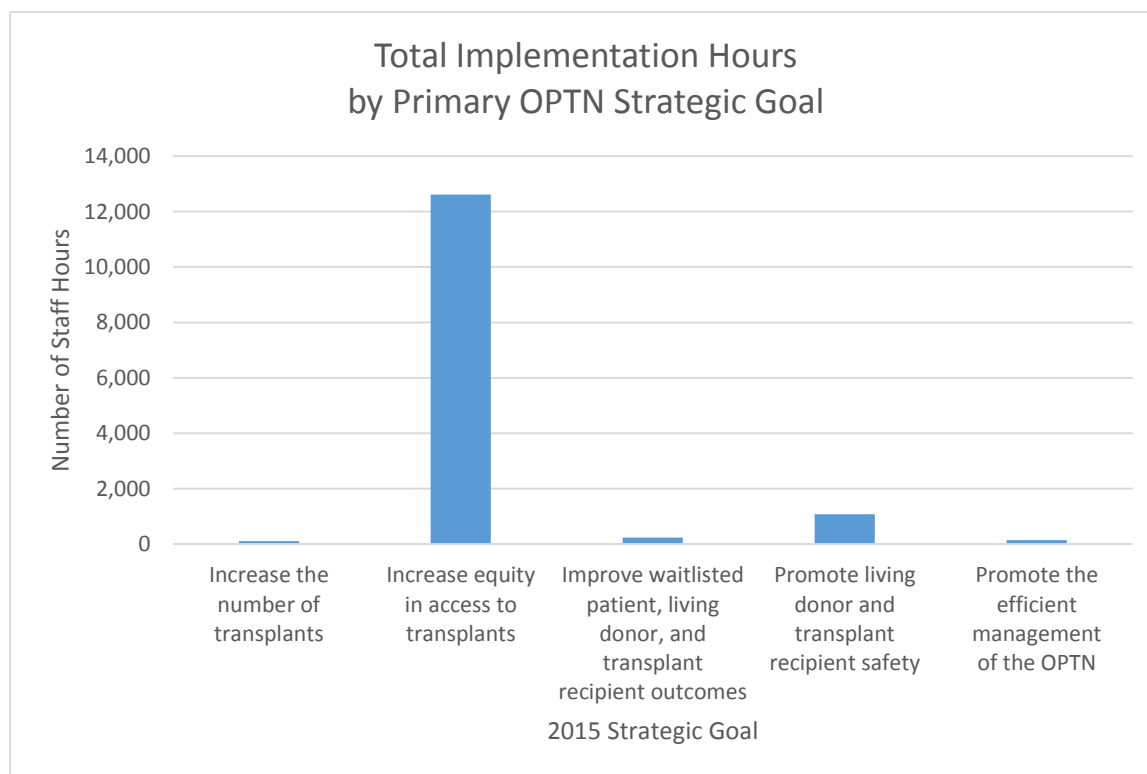
For the upcoming December 2016 Board meeting, most of the implementation hours are in one proposal: Modification of the Heart Allocation System.

#### 4. Current Proposals by Strategic Plan Goals under Board Consideration

The 2015-18 OPTN Strategic Plan has been the guide for project work. Proposals must address a primary key goal. Estimates refer to level of effort that is attributed to the primary goal. The key goals are:

- Goal 1: Increase the number of transplants
- Goal 2: Provide equity in access to transplants
- Goal 3: Improve waitlisted patient, living donor, and transplant recipient outcomes
- Goal 4: Promote living donor and transplant recipient safety
- Goal 5: Promote the efficient management of the OPTN

In terms of project size, the largest number of total implementation hours (n=12,610) will promote Strategic Plan Goal 2: *Provide equity in access to transplants* and then the next largest number will promote Strategic Plan Goal 4: *Promote living donor and transplant recipient safety* (n=1,080). The chart and table below show aggregate and individual estimates by each Strategic Plan Goal.



Of the nine proposals under Board consideration, two proposals align to Goal 1: Increase the number of transplants. One proposal aligns with Goal 2: Provide equity in access to transplants. One proposal aligns with Goal 3: Improve waitlisted patient, living donor, and transplant recipient outcomes. The majority of proposals (n = 3) further Goal 4. Two proposals align to Goal 5: Promote the efficient management of the OPTN.



Project Title	Sponsoring Committee	Total Implementation Hours	Ongoing Hours (3 year time period)
Changes to HCC Criteria for Auto Approval	Liver and Intestines	1040	30
Modification of the Heart Allocation System	Thoracic	11570	950
Ethical Considerations of Imminent Death Donation	Ethics	10	10
Modification of Existing and Potential New Requirements for the Informed Consent of Potential Living Donors	Living Donor	160	60
Review Existing White Papers for Accuracy and Relevancy	Ethics	0	10
Define Transplant Hospital	Membership & Professional Standards	1050	10
Subspecialty Board Certification for Primary Liver and Heart Transplant Physicians	Membership & Professional Standards	30	10
Consider primary surgeon qualification - primary or first assistant on transplant cases	Membership & Professional Standards	10	100
Updating the Bylaws' Primary Kidney Transplant Physician Requirements	Membership & Professional Standards	30	10
<b>TOTALS:</b>		<b>13,900</b>	<b>1,190</b>

## 5. Combined Costs for All Proposals

### UNOS

Impact Snapshot	Staff Hours Estimate	Staff Cost Estimate
Total Implementation Estimate	13,900	\$1,013,100
Ongoing Review Estimate	1,190	\$28,100

If all requests are approved, they will require 13,900 hours of staff time to implement and will cost \$1,013,100. There are 12,460 IT implementation hours with these proposals. IT implementation hours represent 89.6% of all implementation hours.

### OPTN/UNOS Members

Impact Snapshot	OPO	Lab	Transplant Center
Total Implementation Estimate	Minimal	\$2,500	\$29,500
Ongoing Review Estimate	Minimal	\$30,000	\$91,750

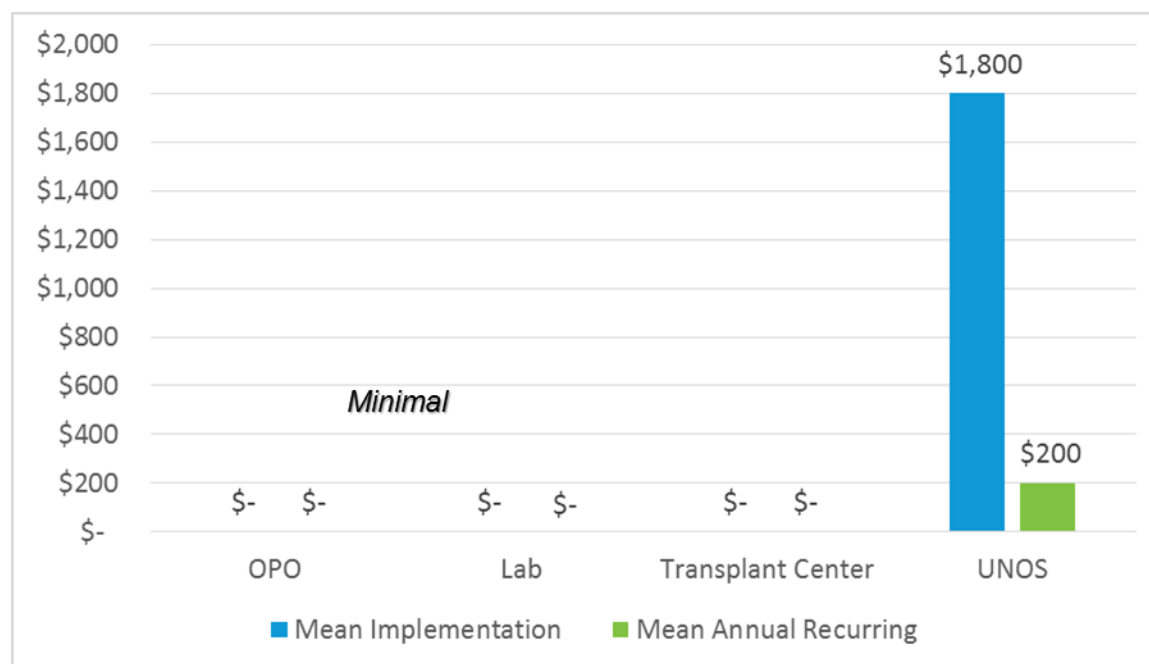
Figures are estimated average additional costs for one member for all nine proposals combined, if approved.

## *Proposal Impact Summaries*

### **Subspecialty Board Certification for Primary Liver and Heart Transplant Physicians**

#### Executive Summary

OPTN Bylaws require that a designated liver transplant program’s primary liver transplant physician must have “current board certification in gastroenterology.” The OPTN/UNOS Membership and Professional Standards Committee (MPSC) is increasingly receiving liver program key personnel applications that propose a primary transplant physician who meets all the Bylaws’ requirements except they have current board certification in transplant hepatology, with lapsed gastroenterology board certification. The MPSC generally feels that these individuals meet the intent of the key personnel Bylaws and that they are qualified to serve as a liver program’s primary transplant physician; however, it ultimately rejects these applications because the individual does not fulfill the explicit requirements in the Bylaws. Although not presented as frequently, the MPSC is also aware of a subspecialty board certification created for cardiologists by the American Board of Internal Medicine- advanced heart failure and transplant cardiology. This proposal modifies the board certification requirement for primary liver transplant physician applicants to include current board certification in transplant hepatology or current pediatric transplant hepatology certification of added qualification as acceptable options. Similarly, this proposal also modifies the board certification requirement for primary heart transplant physician applicants to also include current board certification in advanced heart failure and transplant cardiology as an acceptable option. Requiring board certification for a transplant program’s primary physician that entails more transplant-specific training stands to improve outcomes and promote patient safety for candidates on the waiting list, living donors, and transplant recipients. Additionally, modifying OPTN Bylaws to reflect current practice helps promote the efficient management of the OPTN.



Discussion: Project Size/Complexity

UNOS

Implementation hours for Member Quality and Research total 30 hours.

Ongoing hours are minimal.

Project Size = **Very Small**

MEMBER

*Transplant Center*

The implementation effort for Transplant Centers is minimal, as there is already a framework in place to verify physician requirements. Internal policy updates will require minimal staff time.

Implementation costs include staff training on requirements, internal policy updates, and time to collect and enter data.

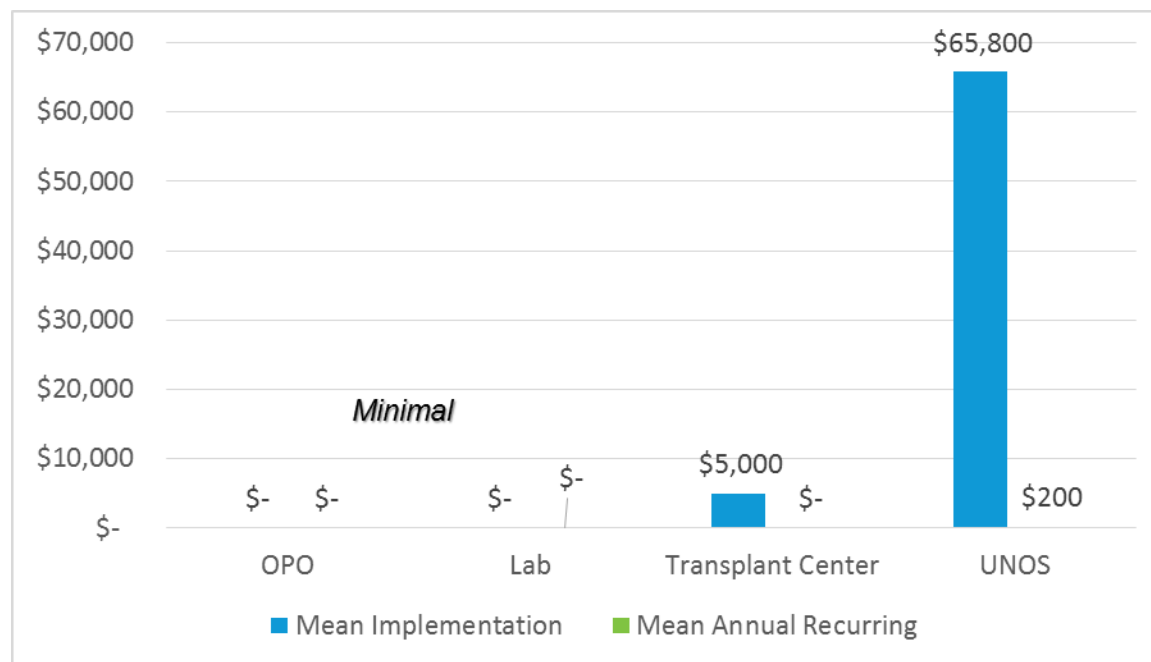
*OPOs and Labs*

OPOs and Labs are not affected by this proposal.

## Updating the OPTN Definition of Transplant Hospital

### Executive Summary

Updates to how the OPTN defines a transplant hospital are needed to better describe attributes requiring consideration by the Membership and Professional Standards Committee (MPSC) when it reviews OPTN membership and transplant program designation applications. A transplant hospital member is currently defined by OPTN Bylaws as “a membership category in the OPTN for any hospital that has current approval as a designated transplant program for at least one organ” and by OPTN Policy as “a health care facility in which transplants of organs are performed.” A lack of distinguishing detail in these definitions has proven to be problematic when assessing the membership of healthcare institutional configurations consisting of multiple hospitals performing transplants of the same organ type at geographically separated sites. The goal of this proposal is to better define the basic accountable unit in which organ transplantation occurs so that meaningful, accurate, and conclusive assessments can be made regarding transplant program performance with patient safety, patient outcomes, and overall compliance with approved OPTN obligations.



### Discussion: Project Size/Complexity

#### UNOS

Major implementation includes 600 hours in which Member Quality processes new forms from all transplant hospitals. Additionally, Member Quality and IT work will work together to modify requirements in a system used to record and track memberships.

Project Size = **Large**

## MEMBER:

*Transplant Center*

Implementation timeframe for Transplant Centers is minimal, estimated at three months for most centers. Time may be needed for staff to adjust any new or changed program criteria.

Implementation costs to transplant centers may result from additional staff hours to collect new or different data to apply for program certification. Centers in which programs are geographically separate may be additionally burdened with administrative time in the certification process. Examples of geographic separation may include a pediatric and an adult program or organ-specific separate locations. Two Veterans Affairs (VA) transplant programs must process through the entire membership application process. Any transplant programs that do not meet explicit campus configuration included in the proposal will incur additional burden in engaging the MPSC to justify approval.

Recurring annual costs are minimal for all centers, once implemented.

*Transplant Center Methodology Notes:*

- One-time implementation cost impact estimate (for most transplant centers) of \$5,000 is based on 40 hours of staff implementation time at a blended rate of \$125/per hour. The rate includes administrators, doctors, and senior management.
- Recurring annual additional budget cost post-implementation is minimal, except for staff time in executing new or additional protocol.
- There is no cost savings.

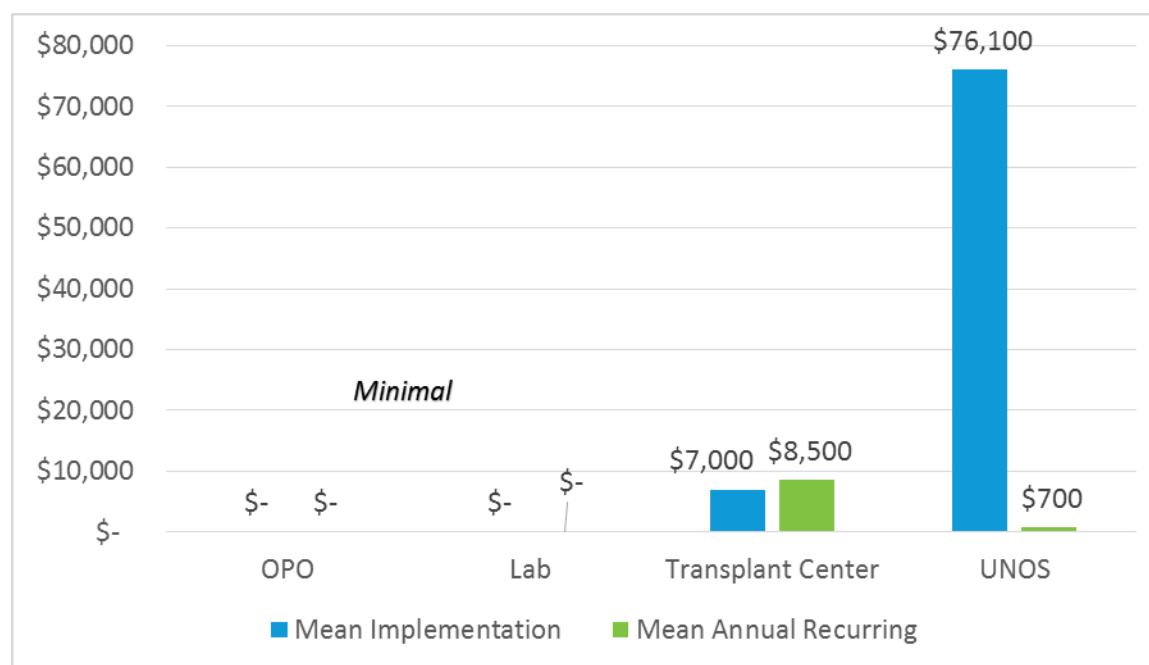
*OPOs and Labs*

OPOs and Labs are not affected.

## Changes to HCC Criteria for Auto Approval

### Executive Summary

The current criteria for automatic approval of hepatocellular carcinoma (HCC) exceptions for liver candidates is problematic, in that they apply to patients who may do well without liver transplant, those who have a poor prognosis after transplant, and potentially excludes patients that may benefit from liver transplant. Additionally, it has been widely shown that successful downstaging of HCC in selected patients is associated with excellent post-transplantation outcome. However, language describing the eligibility criteria for candidates suitable for HCC downstaging through local-regional treatment is absent from current OPTN/UNOS policy, yet nearly all regions currently approve patients who present outside of T2 criteria and have undergone downstaging to within T2. This proposal seeks to make a more consistent national policy regarding HCC patients, increase equity in access to transplants and improve waitlisted patient and transplanted recipient outcomes through modifications to the current standardized HCC exception process.



### Discussion: Project Size/Complexity

#### UNOS

Major implementation hours include 920 IT hours and 30 Member Quality hours to update templates and forms, perform site survey, allocation reviews, and member education.

Ongoing effort is minimal.

Project Size = **Large**

## MEMBER

*Transplant Center*

Implementation timeframe for Transplant Centers is minimal, estimated at two months for most centers. Time may be needed to implement systems to track patients in greater detail. System changes include workflow changes, reports, and scheduling changes.

Existing workflow process, unique to each center, is the variable that most impacts implementation and ongoing financial resources. Additional staff time is needed to ensure patients meet all criteria for downstaging, exceptions, or listing. Small centers with fewer staff members may be most burdened, while larger centers may be able to more easily add additional staff hours and absorb financial impact.

*Transplant Center Methodology Notes:*

- One-time implementation cost impact estimate (for most transplant centers) of \$7,000 is based on 100 hours of staff implementation time at a blended rate of \$70/per hour and includes medical and administrative staff.
- Recurring annual additional budget cost post-implementation is estimated at \$4,000-\$13,000 and based on an average of \$50 /per hour (RN/MA only) rate at 3-5 additional staff work hours per week for 52 weeks per year.
- There is no cost savings.

*OPOs and Labs*

OPOs and Labs are not affected.

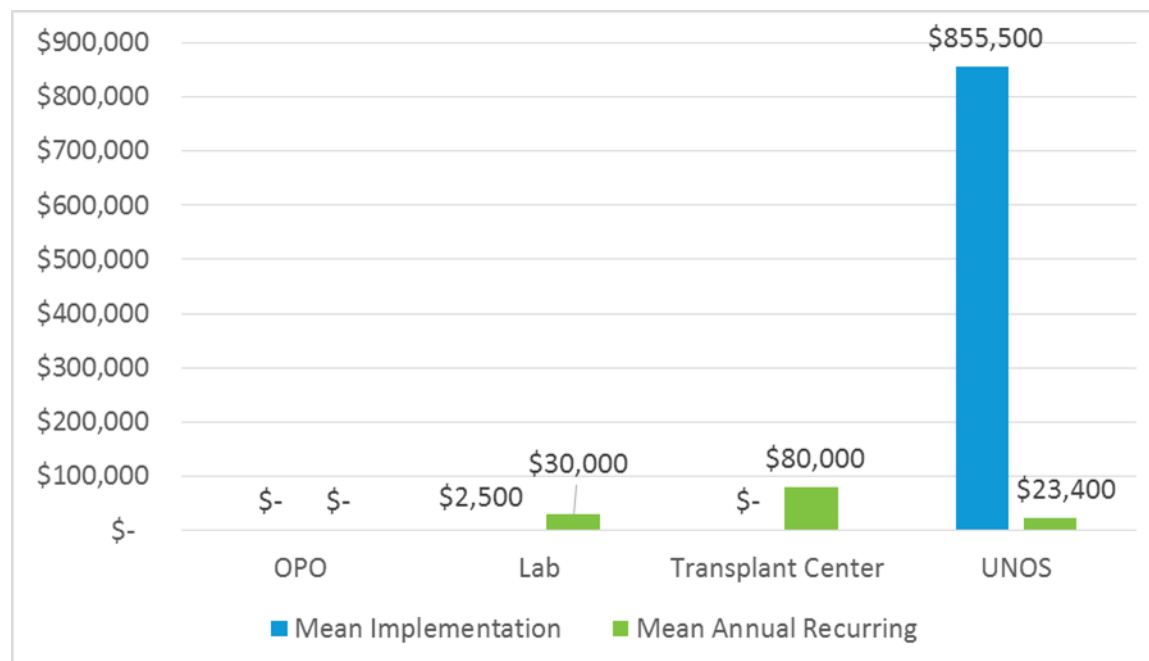


## Modification of the Heart Allocation System

### Executive Summary

The Thoracic Organ Transplantation Committee (the Committee) proposes modifications to the adult heart allocation system to better stratify the most medically urgent heart transplant candidates, reflect the increased use of mechanical circulatory support devices (MCS) and prevalence of MCS complications, and address geographic disparities in access to donors among heart transplant candidates. In response to significant comments received during the first round of public comment, and based on additional feedback and consensus-building after public comment, the Committee proposes the following modifications to the original proposal:

- Refining and tightening the qualifying criteria for candidates supported by veno-arterial extracorporeal membrane oxygenation (VA ECMO), percutaneous circulatory support devices, intra-aortic balloon pumps (IABP), and multiple inotropes to require evidence that these candidates are supported by these therapies for treatment for cardiogenic shock, rather than qualifying based on the presence of the therapy alone
  - o Criteria for determining presence of cardiogenic shock are based on American Heart Association definitions or the presence of end-organ dysfunction
- Placing additional restrictions on the duration for candidates may remain in statuses 1 through 3
  - o Candidates supported by the therapies above, which are intended for short-term, acute therapy for cardiogenic shock, will be limited to 14 days in the respective status unless the candidate exhibits contraindications to use of a durable device and has failed a weaning attempt
- Clarifying which mechanical circulatory support devices qualify a candidate for certain statuses, including limiting status 1 to candidates supported for biventricular failure with surgically-implanted, non-endovascular devices
- Requiring regional review boards to review cases external to their region
- Limiting the proposed broader geographic sharing scheme for the most urgent candidates to donation service area and Zone A (instead of through Zone B)
- Modifying the pediatric donor allocation sequence to limit potential negative impacts of the new adult heart allocation system on pediatric candidates
- Explicitly specifying the additional proposed data collection for the development of a heart allocation score in the future



### Discussion: Project Size/Complexity

#### UNOS

Implementation is an enterprise-wide effort, requiring 11,040 hours in IT programming. Changes to the Waitlist and DonorNet systems, as well as UNOS staff systems are necessary. This is an entire overhaul of an allocation system similar to the revised kidney allocation system.

Substantial effort is also required of Policy (220 hours), Research (100 hours) and Instructional Innovations (100 hrs.) to assist with system changes, data collection, and member education on new policy.

Ongoing annual effort includes 293 IT hours.

Project Size = **Enterprise**

#### MEMBER

##### Lab

Implementation timeframe for all labs may be a few weeks. Staff training on the new allocation system and updating internal policies account for implementation. No additional staff are required to enact or maintain the changes.

Implementation costs can include staff training. Number of staff and salary will vary by lab. While unlikely, increased volume in crossmatch and testing may require purchase of additional instrumentation to support the increase.

Most labs should be able to absorb additional testing volume without additional equipment purchase, since similar tests are already performed for other organ types. If not, the cost for a

Luminex analyzer to test for antibodies is approximately \$50,000, with a \$5,000 annual service fee.

Since the proposal simply requires that CPRA data be reported, and does not mandate extra testing, it is unlikely that increased recurring cost due to testing will be realized at all. In the case of increased testing, recurring costs account for additional antibody testing and crossmatching supplies for highly sensitized heart patients and any potential staff overtime hours to complete the additional work volume. The volume of additional virtual and physical crossmatches can be dependent on the size of the transplant centers served by the lab, accounting for a wide potential recurring cost range (\$1,000 - \$60,000). Costs can include purchase of additional reagents for testing, crossmatch supplies, and staff hours in testing and analysis.

*Lab Methodology Notes:*

- Labs assume running crossmatches and tests for an additional 2-8 sensitized patients (or an active list of 25 (small heart program) to 60 patients (larger heart program) per year. It is assumed about 10% of wait-listed patients might be considered "sensitized."
- Unless volume is substantial, most labs should be able to absorb any additional costs.

*Transplant Center*

Implementation timeframe for transplant centers is estimated at three months to train staff and update internal policies. The costs are minimal.

Recurring costs are substantial. Broader sharing increases the number and distance/time of additional heart fly outs. A range of additional fly outs is estimated at 3 additional hearts for smaller centers to 11 at larger centers, potentially costing \$30,000-\$110,000 annually. Longer case time results in additional OPO staff time billed to Transplant centers. OPOs coordinate cases and arrange logistics, passing costs to transplant centers. Transplant centers receive reimbursement from insurance, but insurance reimbursement may not equal the full cost of the fly out. Additional transplant center staff time to record data for additional transplant volume may be required.

*Transplant Center Methodology Notes:*

- An average flight is estimated at \$10,000
- Hospital cost per hour for heart transplant case is estimated at \$750
- 20% of heart transplants are estimated to require flights

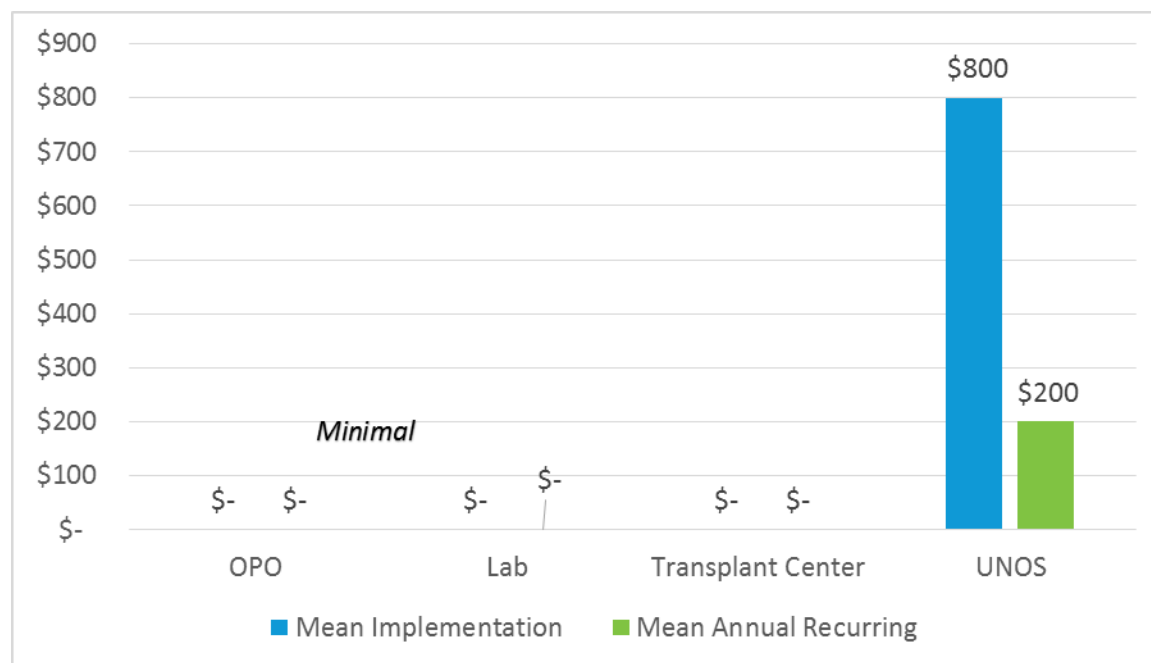
*OPO*

Implementation and recurring costs are minimal. If additional heart transplants and/or heart fly outs increase, additional staff time may be needed to coordinate. OPOs without call centers may be more burdened by additional staff time, but the minimal increase can likely be absorbed. Increased cost of heart fly outs and increases in medical supply purchases are passed to transplant centers.

## Ethical Considerations of Imminent Death Donation

### Executive Summary

Beginning in 2014, the Ethics Committee (the Committee) coordinated an inter-committee work group to consider the ethical implications of Imminent Death Donation (IDD). IDD is a term that has been used for the recovery of a living donor organ immediately prior to an impending and planned withdrawal of ventilator support expected to result in the patient’s death. The work group’s motivations were to compare the existing practices of attempting donation after cardiac death (DCD) to the practice of LD-PPW (“live donation prior to planned withdrawal”). After a thorough examination of the potential of LD-PPW, the Committee ultimately determined that there could be circumstances where LD-PPW may be ethically appropriate and justified by the potential benefits to donors, donor families and recipients. However, based on the responses and substantial concerns from nine other Committees, the Ethics Committee decided to discontinue work on LD-PPW because of its potential risks at this time, due to a lack of community support and substantial challenges to implementation. In the future, it may be possible to adequately address those challenges through additional research or careful policy development or revision.



### Discussion: Project Size/Complexity

UNOS

Implementation and ongoing effort is minimal.

Project Size = **Very Small**

MEMBER

No impact.

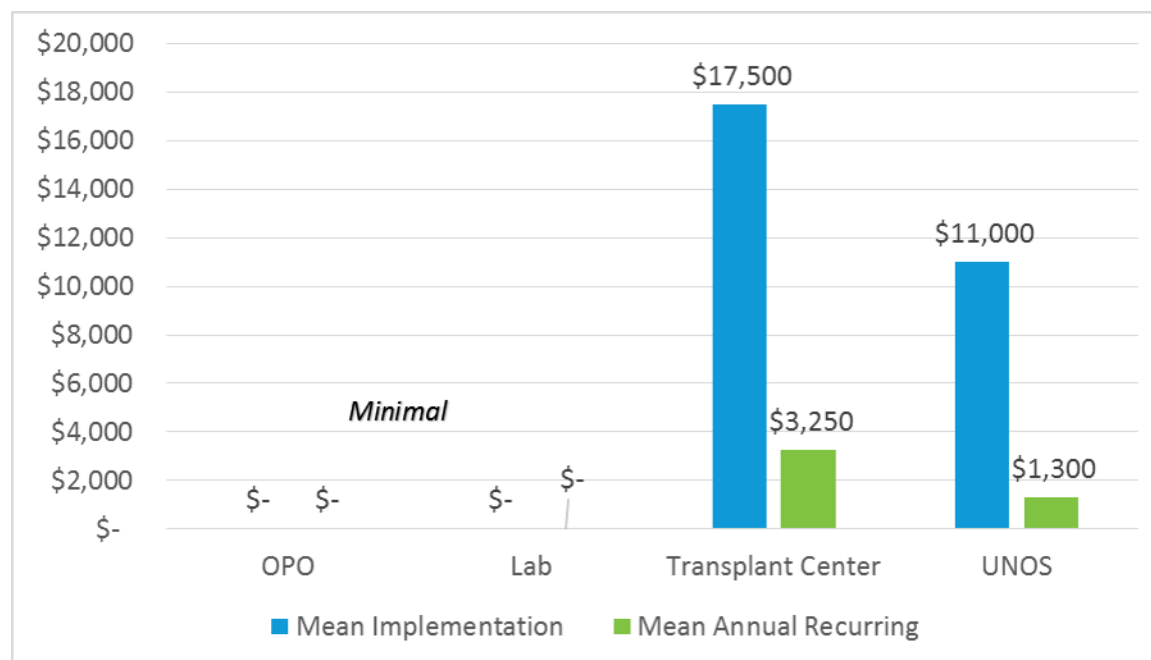
## Modifications to Informed Consent Requirements for Potential Living Donors

### Executive Summary

In February 2013, the OPTN/UNOS implemented the current requirements for the informed consent of living kidney donors. Informed consent requirements for living liver, pancreas, intestine and lung donors followed in 2014. Since initial implementation, several developments support the need to update and clarify the current informed consent policy requirements including:

- Publication of new evidence on living kidney donor health outcomes
- Consensus-based recommendations from professional societies that the new information regarding the health outcomes for living kidney donors should be disclosed as part of the informed consent process
- Release of living donor program-specific reports (PSRs) by the Scientific Registry of Transplant Recipients (SRTR)
- Reports from living donor program site surveys identifying areas of existing policy language that have been frequently misunderstood by living donor recovery programs

The OPTN/UNOS Living Donor Committee (Committee) reviewed the informed consent requirements for living donors and proposes clarifying existing requirements and adding other new requirements. The proposal also includes related changes to the informed consent requirements for kidney paired donation, and modification and elimination of some related OPTN Bylaws requirements.



### Discussion: Project Size/Complexity

#### UNOS

The majority of hours (80) is required from IT to program changes. Communications and Regional Administration each estimate 20 hours to communicate changes to members.

Implementation and Ongoing effort is minimal.

Project Size = **Very Small**

#### MEMBER

##### *Transplant Center*

Implementation timeframe for Transplant Centers is estimated at six months for most centers. Time is needed primarily to conduct legal review, implement process and workflow changes, and create print materials and to educate existing staff and patients on new requirements.

Implementation cost to transplant centers results from additional staff hours. The legal review team conducts analysis and approves new requirements, project management staff implements changes, and administrative and clinical staff educates existing staff and patients on new requirements. Printing costs exist, as well, but may be minimal. Cost and financial burden varies based on size of transplant program.

##### *Methodology Notes:*

- One-time implementation cost impact estimate (for most transplant centers) of \$10,000-\$25,000 is based on 200-500 hours of staff implementation time at a blended rate of \$50/per hour.
- Recurring annual additional budget cost post-implementation ranges from \$1,500-\$5,000 for annual legal team review of policy requirements and printing. Cost depends on size/volume of transplant program.
- There is no cost savings.

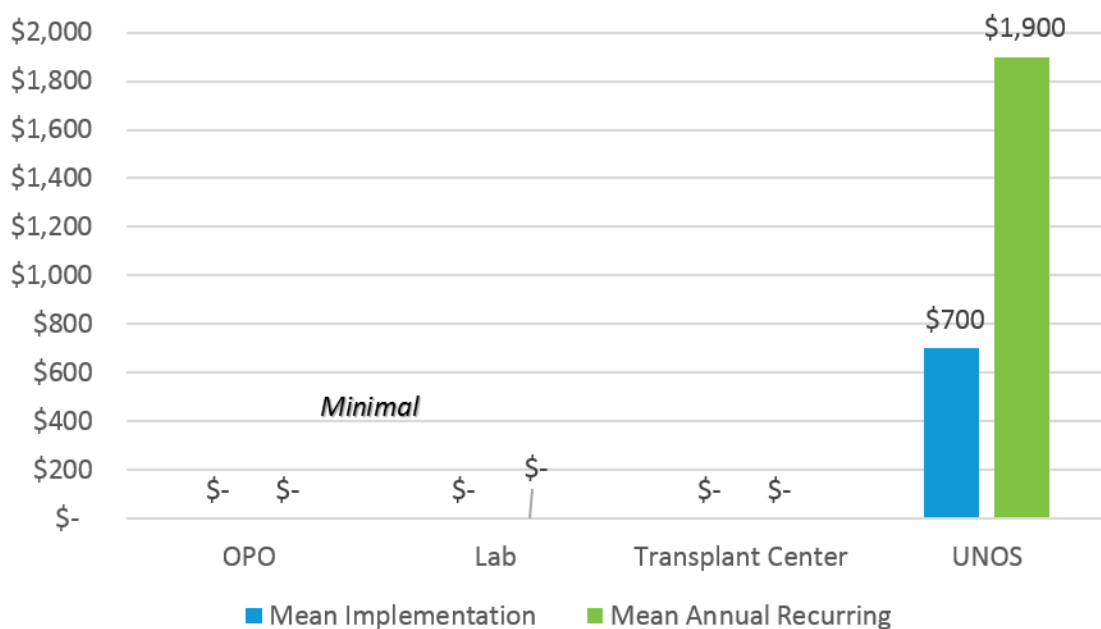
##### *OPOs and Labs*

OPOs and Labs are not affected.

## Consider Primary Transplant Surgeon Requirement – Primary or First Assistant on Transplant Cases

### Executive Summary

Primary transplant surgeons are required to have performed a set number of transplants and procurements as the “primary surgeon or first assistant.” Primary thoracic transplant surgeons must perform a certain number of these procedures as the primary surgeon, but the Bylaws do not specify this for abdominal surgeons. Considering this, and that the responsibilities of a surgical first assistant are not consistent across institutions, the MPSC has raised concerns that surgeons could qualify as a transplant program’s primary surgeon though they may have never performed critical surgical transplant functions that would be expected of a primary transplant surgeon leading a designated program. This proposal recommends that an abdominal surgeon applying through the clinical experience pathway must have performed at least half of the required transplants and procurements as the primary or co-surgeon. Additionally, this proposal recommends that all cases accepted towards transplant training program requirements should also count towards OPTN/UNOS Bylaws requirements for all surgeons applying through training pathways. Requiring all primary transplant surgeons applying through clinical experience pathways to have performed a certain number of transplants and procurements as the primary surgeon is intended to promote patient safety and improve outcomes by assuring that each transplant program is led by individuals who have sufficient training and experience in organ transplantation.



### Discussion: Project Size/Complexity

#### UNOS

Implementation effort is minimal.

Ongoing effort annual effort (100 hours) includes monitoring and program qualification through Member Quality.

Project Size = **Very Small**

MEMBER

*Transplant Center*

Implementation timeframe for Transplant Centers is minimal, estimated at two months for most centers. Time may be needed to adjust existing databases and implement any changes or additions to data quality review.

Implementation cost to transplant centers may result from minimal additional staff hours to adjust for data collection, analysis, and case review documentation for the surgeon role.

There is no cost savings.

*OPOs and Labs*

OPOs and Labs are not affected.

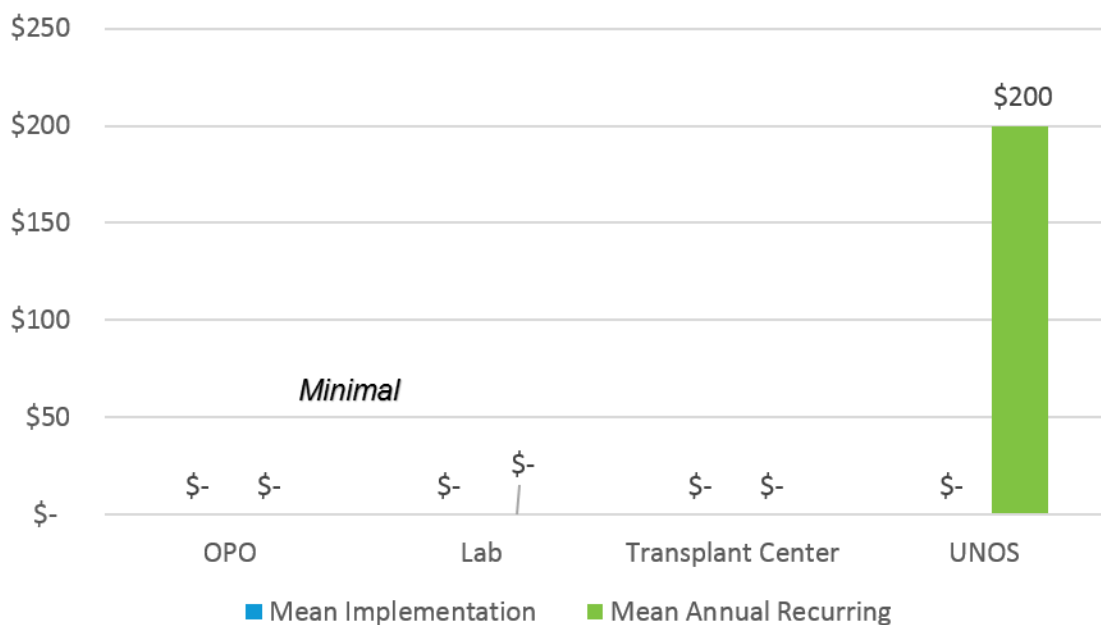


## Review Existing White Papers for Accuracy and Relevancy:

1. Ethical Implications of Imminent Death Donation
2. Ethics of Deceased Donor Recovery without Requirement for Explicit Consent or Authorization
3. Split Versus Whole Liver Transplantation

### Executive Summary

Beginning in 1993, the Ethics Committee (the Committee) developed a series of white papers that are available through the OPTN website. In 2014, the Committee began a systematic review of these white papers to evaluate if each of the white papers were accurate and relevant, and therefore valuable resources for the transplant community. The original white paper addressing presumed consent was produced in 1993, and was written in response proposed presumed consent legislation under consideration in Maryland and Pennsylvania. The Committee determined that this white paper was neither accurate nor relevant. Over the past year, the Committee completed a line-by-line review and a substantive revision of the white paper. The white paper received a new title, contains new content addressing current issues with presumed consent which is supported by citations to current research and literature. The white paper addressing split versus whole liver transplantation (2004) was also determined to require revision. Over the past year, the Committee completed a substantive revision of the white paper addressing split liver allocation, which includes recommendations for changes to the liver allocation, an extensive set of citations, new appendices, and new illustrations.



### Discussion: Project Size/Complexity

#### UNOS and MEMBER

Implementation hours for UNOS and Members are minimal.

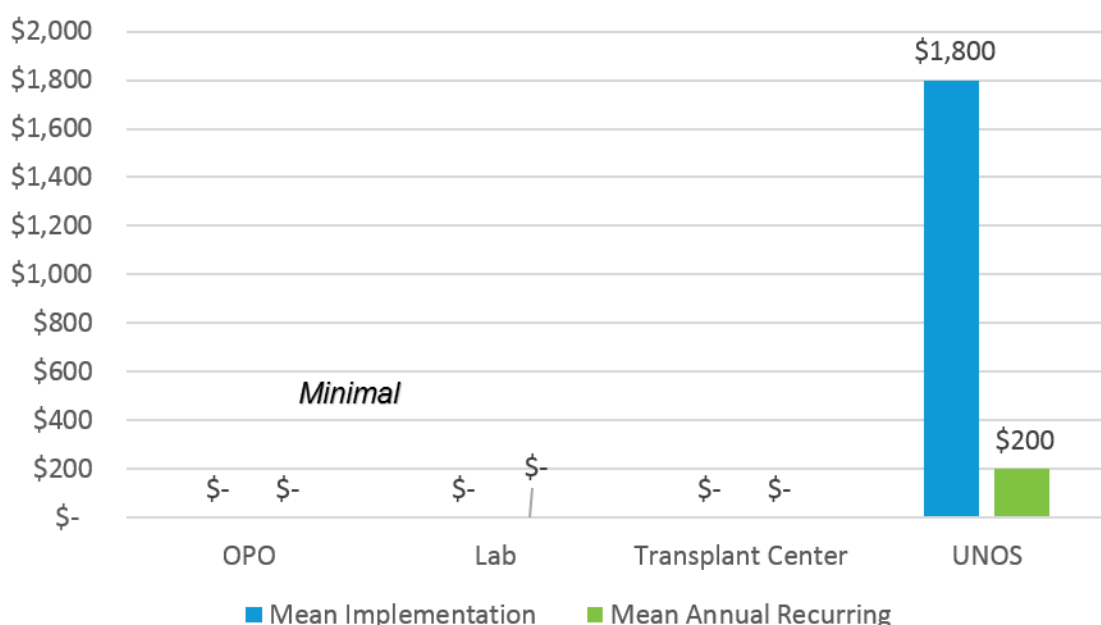
Ongoing annual hours for UNOS and Members are minimal.

Project Size = **Very Small**

## Updating Primary Kidney Transplant Physician Requirements

### Executive Summary

Fellowship training requirements have historically served as the foundation for key personnel requirements in OPTN/UNOS Bylaws. Primary kidney transplant physician requirements in the Bylaws have not evolved with nephrology fellowship training. For example, the Bylaws currently do not accommodate transplant nephrology fellowships longer than 12 months which have been developed for fellows wishing to pursue transplantation research during their training period, nor do they include requirements pertaining to the evaluation of living donors or potential kidney recipients which are now standard fellowship requirements. The goal of this proposal is to update the Bylaws to better align with transplant nephrology fellowship requirements.



### Discussion: Project Size/Complexity

#### UNOS

No substantial implementation or ongoing staff effort exists.

Project Size = **Very Small**

#### MEMBER

##### Transplant Center

Implementation timeframe for Transplant Centers is minimal, as there is already a framework in place to verify physician requirements. Internal policy updates will require minimal staff time.

##### OPOs and Labs

OPOs and Labs are not affected.