Impact Summaries

OPTN/UNOS BOARD OF DIRECTORS

June 4-6, 2017

Richmond, VA

Table of Contents

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. 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**. Charts are included with estimated cost information for both UNOS staff and OPTN/UNOS Member organizations.

The remaining portion of the **Impact Summary** estimates the resources that will be required following OPTN/UNOS Board 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 2017-2018 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 Board actions can affect the functionality of existing programming operations. This requires maintenance resources when 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 hospitals, 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 scheduled 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 ranges 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.

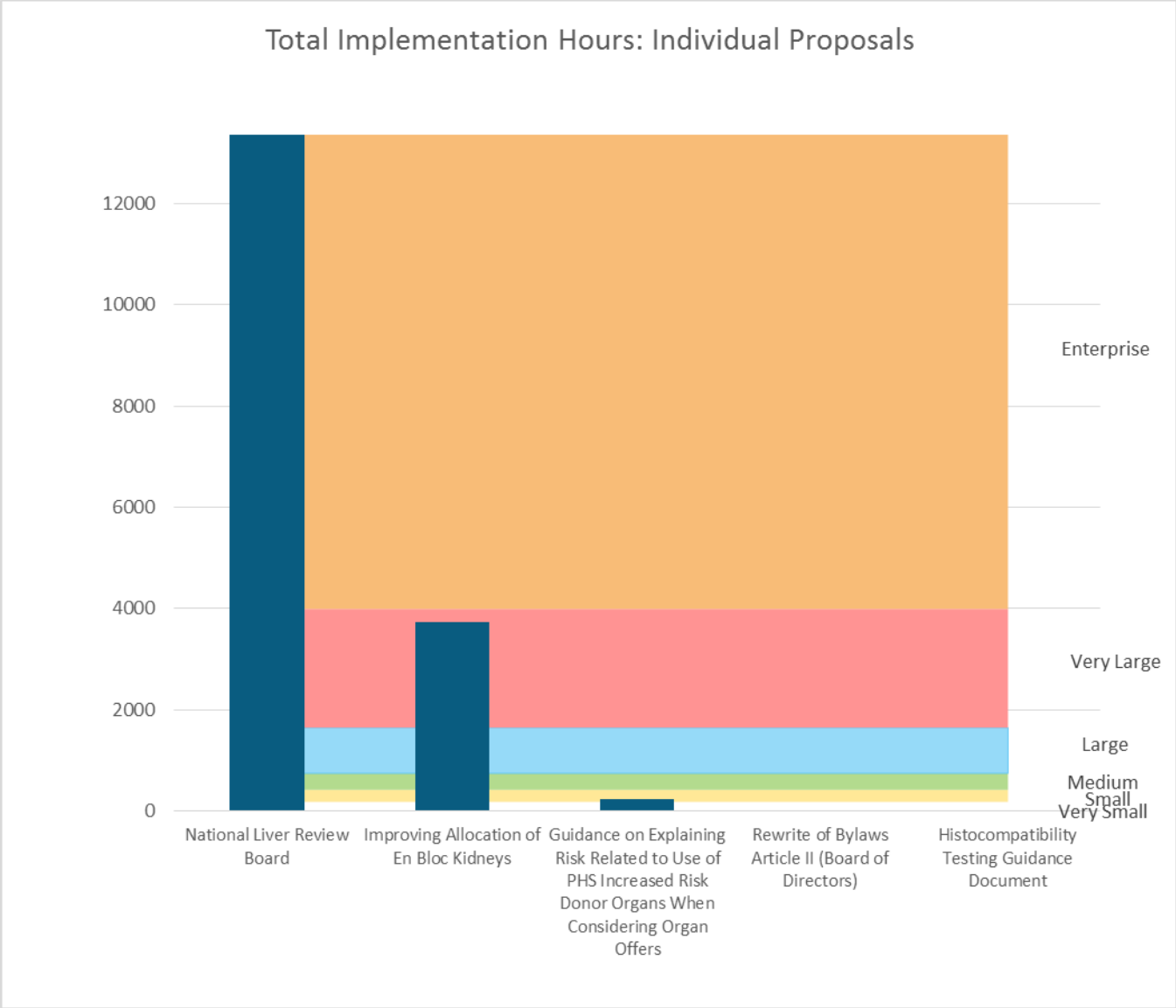
PMO Guidelines for Identifying Project Size

Project Size	Estimated Hours	Historical Examples
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 that the Board reviewed for approval. The average number of implementation hours estimated for projects going to the Board meeting from November 2014 through June 2017 equals 16,545. The average number of programming hours over the past six cycles is 12,567. Using these averages, IT work typically represents 76% 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 22,240 (June 2015).

For the upcoming June 2017 Board meeting, the estimates are 17,330 hours (all implementation) and 15,720 (IT implementation only). IT hours represent 90.7% of all implementation efforts for this upcoming cycle. For the upcoming June 2017 Board meeting, most of the implementation hours are in one proposal: National Liver Review Board.



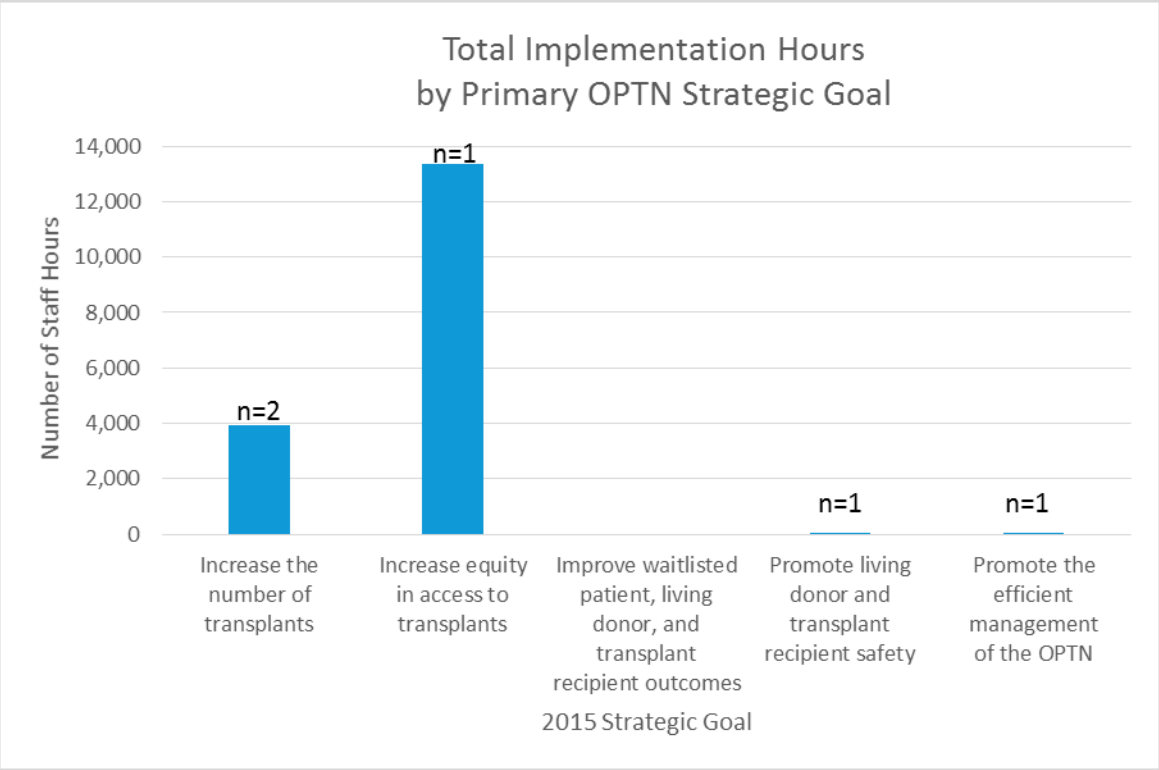
The chart above shows each proposal going to the Board in June 2017 by total implementation hours. The horizontal bands reflect the PMO project sizes as explained on page 5. Two of the proposals require IT programming hours.

4. Current Proposals by Strategic Plan Goals under Board Consideration

The 2015-18 OPTN Strategic Plan has been the guide for project work. When the Policy Oversight Committee and Executive Committee review new project proposals, they assign the project to a primary key goal. Estimates refer to the 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=13,350) will promote Strategic Plan Goal 2*: Provide equity in access to transplants* and then the next largest number will promote Strategic Plan Goal 1: *Increase the number of transplants* (n=3,955). The chart and table below show aggregate and individual estimates by each Strategic Plan Goal.



Of the five proposals under Board consideration, two proposals align with Goal 1: Increase the number of transplants. One proposal aligns with Goal 2: Provide equity in access to transplants. No proposals align with Goal 3: Improve waitlisted patient, living donor, and transplant recipient outcomes. One proposal furthers Goal 4, to promote living donor and transplant recipient safety, and one proposal aligns with Goal 5: Promote the efficient management of the OPTN.

Project Title	Sponsoring Committee	Total Implementation Hours	Ongoing Hours (3 year time period)
National Liver Review Board	Liver and Intestines	13,350	1,120
Improving Allocation of En Bloc Kidneys	Kidney	3,730	220
Guidance on Explaining Risk Related to Use of PHS Increased Risk Donor Organs When Considering Organ Offers	Ad Hoc Disease Transmission Advisory	225	15
Histocompatibility Testing Guidance Document	Histocompatibility	10	10
Rewrite of Bylaws Article II (Board of Directors)	Executive	15	12
		17,330	**1,377**

5. Combined Costs for All Proposals

UNOS

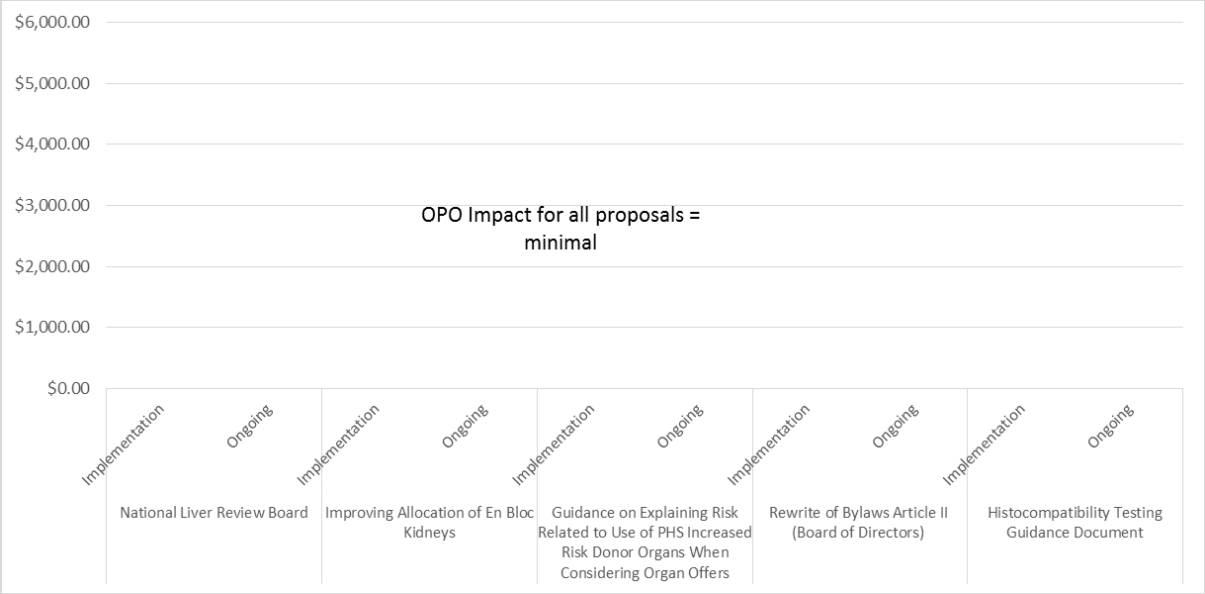
Impact Snapshot	Staff Hours Estimate	Staff Cost Estimate
Total Implementation Estimate	17,330	$1,265,998.50
Ongoing Review Estimate (Annual, out to three years)	1,377	$100,344.42

OPTN/UNOS Member Fiscal Impact Ranges

The following charts indicate potential financial impact *ranges* for both implementation and annual ongoing cost for one member OPO, Hospital, or Lab. A comprehensive narrative of the impact of each proposal on members follows the charts below.

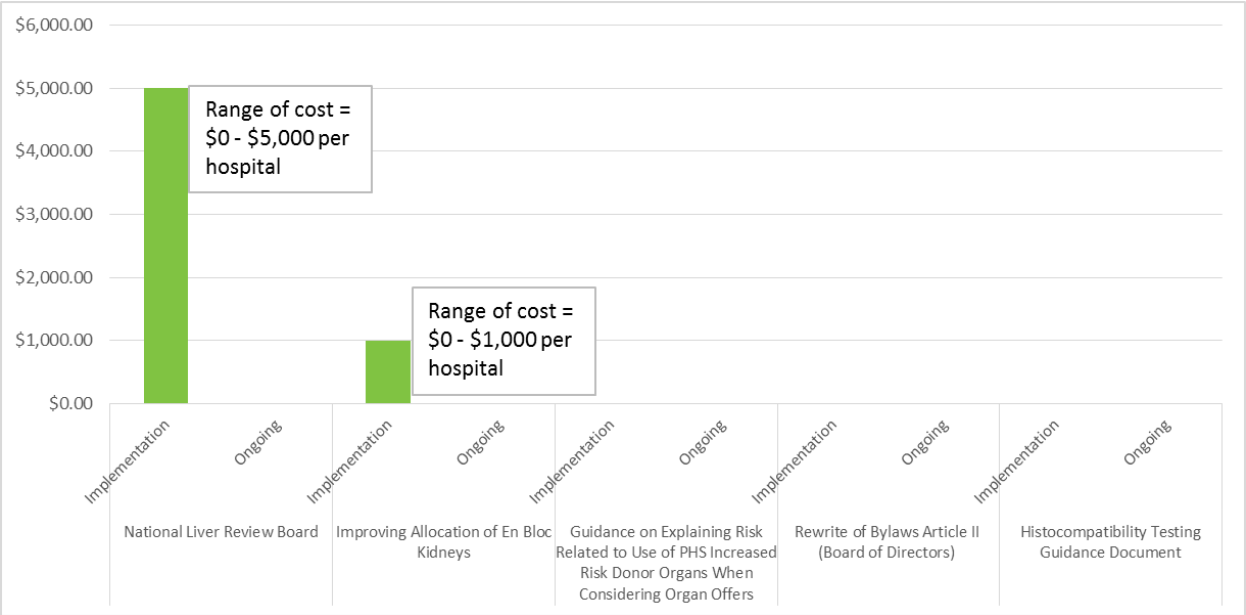
OPO

All proposals for this cycle should require no or minimal effort for OPO members.



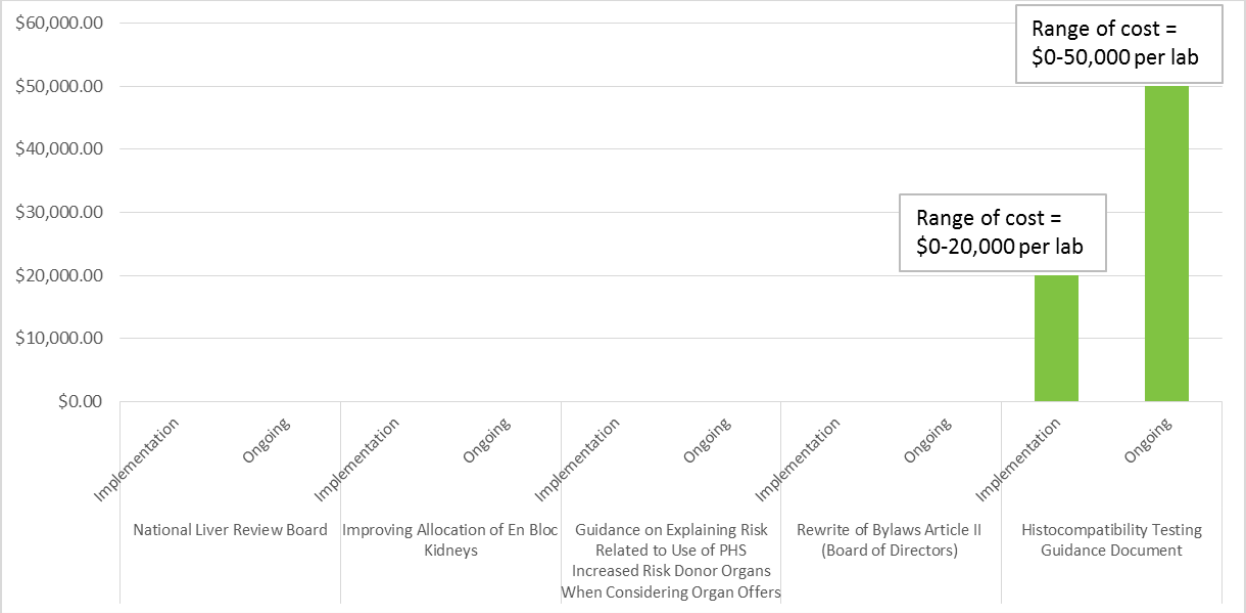
Hospital

Implementation for the *National Liver Review Board* proposal could financially impact hospitals up to $5,000, while *Improving Allocation of En Bloc Kidneys* could cost up to $1,000 per hospital. See narratives for more information.



Lab

If lab members implemented all guidance associated with the *Histocompatibility Testing Guidance Document*, implementation could result in up to $20,000 and ongoing cost could be up to $50,000. The high cost would result from no existing infrastructure to support the proposal, which would be rare. See narratives for more information.



Proposal Impact Summaries

National Liver Review Board and Guidance Documents

Executive Summary

Currently there is not a national system that provides equitable access to transplant for liver candidates whose status or calculated MELD or PELD score does not accurately reflect the severity of their disease. Instead, each region has its own review board that evaluates exception requests submitted by the liver transplant programs in its region. Most regions have adopted independent criteria used to request and approve exceptions, commonly referred to as "regional agreements." Some have theorized that regional agreements may contribute to regional differences in exception submission and award practices, even among regions with similar organ availability and candidate demographics. The NLRB seeks to mitigate regional differences in award practices by establishing new voting procedures and giving the Committee the ability to develop national guidance for assessing common requests. Finally, this proposal modifies the score provided for exception candidates by providing the score assigned to exception candidates to a fixed value just below the median MELD at transplant.

In support of the NLRB project, the Committee has developed guidance for specific clinical situations for use by the NLRB to evaluate common exceptional case requests for adult candidates, pediatric candidates, and candidates with hepatocellular carcinoma (HCC).

IMPACT POINTS:

- **ENTERPRISE** = UNOS IT project complexity.
- 13,350 = Implementation all departments
- 1,120 hours = Ongoing (annual) all departments
- Major implementation costs to hospitals include staff time to update internal procedures and appointment of clinicians to the NLRB.
- Hospital implementation time of one to six months is estimated
- Ongoing hospital cost burden is dependent on exception volume, highly variable among regions and centers.
- Clinicians serving as NLRB representatives must dedicate additional work hours to review exceptions.
- Guidance documents do not contain new member requirements. However the assumption in estimating fiscal impact is the members will follow guidelines.

Discussion: Project Size/Complexity

UNOS

IT Implementation effort is enterprise level and includes 12,400 estimated hours for analysis and project management, changes to review board management and processing, and changes to the waitlist.

Instructional Innovations requires a large effort, requiring more than one offering to educate members.

Policy requires a large effort for Liver Committee review throughout implementation.

The majority of ongoing hours is attributed to IT.

MEMBER

Hospital: Major implementation resources include additional staff time to adjust internal process flow and participate in training on new policy and procedures. Administrative staff must collect and report on data required to review exceptions. Clinicians must be appointed and serve as NLRB representatives, requiring time outside of practice to review exceptions. Up to $5,000 in additional clinical and administrative staff time to implement is attributed, but can likely be absorbed by standard staff hours. Institutional technology support may be required to adjust internal systems to collect

data required by the NLRB. Additional data collection burden is dependent on current institutional process and tools. Estimates is based on 5-6 hours training per clinician and minimal administrative staff training.

Cost burden overall is highly dependent on total center volume and number of candidates on the waiting list. While review of exception volume nationally should remain about the same, some regions may experience higher or lower exception review volume compared to the current system, since case review is distributed more evenly among regions in this proposal. There is potential for a decrease in the NLRB's workload, as programming will be implanted to automate repeat applications for HCC candidates whose cases fall.

Implementation timeframe is estimated at one to six months, with complex large programs requiring multiple months to adjust. Institutions should begin implementation of the process immediately if the proposal becomes effective.

Ongoing costs include clinician time and travel in serving as NLRB representative and administrative staff time in recording additional data on candidates. This is dependent on volume.

While no long term cost savings are identified yet, creating the NLRB may streamline the exception process by adapting to a national process. Indirect efficiencies may materialize from considering exceptions uniform and tracking data across institutions.

OPO and Lab: Minimal to no impact.

Improving En Bloc Kidney Allocation

Executive Summary

To mitigate the complications associated with transplanting kidneys from small pediatric donors singly, both kidneys, including the vena cava and aorta, can be transplanted en bloc into a single recipient. However, there are currently several challenges to allocating en bloc kidneys:

- There is currently no OPTN policy regarding allocation of en bloc kidneys
- The KDPI programmed into DonorNet® doesn't consider how kidneys will be used (en bloc or single) or acknowledge the improved function of en bloc kidneys, which could screen medically suitable candidates off the match run. In addition, there are other programming limitations that make en bloc kidney allocation a challenge

The proposed policy resolves these problems by providing explicit direction to organ procurement organizations (OPOs) on when to allocate en bloc kidneys. The policy includes donor criteria regarding the type of kidneys that can be allocated en bloc and mandates that programs must indicate in DonorNet that they accept en bloc kidneys, thus expediting placement of en bloc kidneys to programs that will transplant them. In addition, the Kidney Transplantation Committee proposes masking the KDPI score for en bloc kidney offers to prevent potentially eligible candidates from being screened off the match run for kidneys from high KDPI donors.

IMPACT POINTS:

- **VERY LARGE** = UNOS IT project complexity
- 3,700 hours = Implementation all departments
- 220 hours = Ongoing (annual) all departments
- Minimal OPO and Hospital staff training
- Hospital staff hours (clinical and administrative) and supplies may increase depending on case volume and complication
- Uncertainty around reimbursement for additional provider costs incurred for en bloc kidneys

Discussion: Project Size/Complexity

UNOS

Implementation effort for IT is very large (3,400 hours) due to waitlist and allocation changes. Instructional Innovations requires a small educational effort with this proposal.

The majority of ongoing hours is attributed to IT (140 hours estimated).

MEMBER

OPO: Since en bloc allocations already occur, this proposal increases efficiency in the allocation process. Minimal staff training on new policy allows implementation to be effective immediately to one month. Since volume of en bloc cases is low, the potential financial impact on operations is low.

Hospital: Minimal staff training to implement is required, unless programs are not already participating in en bloc transplants. Implementation can occur immediately and up to two months to allow for staff education. Staff training is estimated to be $0-$1,000 for training hours, but can likely be absorbed with normal operating costs.

Additional time may be required of both administrative and clinical staff to review and prepare pre transplant, manage on call en bloc offers, and complete en bloc transplants. This is dependent on volume and complication of en bloc cases. If additional time and supplies are required, it is undetermined if additional costs are reimbursable. While higher cost cases may result, the volume of en bloc transplants overall is minimal. There are no substantial ongoing cost identified. Potential efficiencies include reduced wait-list maintenance and a reduction of the in-patient stay.

Lab: Minimal or no impact.

Guidance on Increased Risk PHS Donor Organs

Executive Summary

In July 2013, the U.S. Public Health Service (PHS) published new guidelines for reducing human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) transmission through organ transplantation. These new guidelines, called "increased risk" guidelines, replaced earlier guidelines from 1994 called "high risk" criteria. The transplant community has requested assistance explaining relative risk of disease transmission involving increased risk organ donors to potential organ recipients. The OPTN/UNOS Ad-hoc Disease Transmission Advisory Committee (DTAC), in collaboration with the Joint Society Steering Committee, developed this document to inform and facilitate conversations between transplant team members and their patients. The guidance profiles recent peer reviewed literature and OPTN data to describe the risk of undetected disease transmission from PHS increased risk organ donors.

IMPACT POINTS:

- **SMALL** = UNOS project complexity for all departments.
- 225 = Implementation hours all departments
- 105 = Ongoing (annual) hours all departments
- No major financial impact to implement of maintain for hospitals, OPOs, Labs.
- Minimal Hospital staff time needed to update protocols recommended in guidance.
- Guidance documents do not contain new member requirements. However the assumption in estimating fiscal impact is the members will follow guidelines.

Discussion: Project Size/Complexity

UNOS

A small instructional effort is required to implement this proposal.

MEMBER

Hospital: Staff time to adjust protocols for patient discussion and to update any education materials is needed to implement the guidance. Staff time is variable dependent on size of program and existing protocol.

There is no substantial financial impact, as any changes can be completed within normal operations. Implementation is estimated at 1-2 months for most programs.

The number of transplants may go up if programs accept a greater number of increased risk organs, but costs are expected to be reimbursed by insurance.

OPO and Lab: Minimal or no impact.

Rewrite of Bylaws Article II: Board of Directors

Executive Summary

The OPTN/UNOS Executive Committee is currently reviewing the structure and recruitment process for the OPTN/UNOS Board of Directors. As part of that review, the Executive Committee has identified improvements that are needed in the Bylaws governing the structure and operations of the Board of Directors, the Executive Committee, and the Nominating Committee. The goal of this proposal is to improve transparency about the process for nominating and electing the Board of Directors, filling Director vacancies, and removing voting Directors. The majority of the changes in the proposal seek to better organize and add clarity to Article II: Board of Directors and move current sections within the Article to sections more appropriate for the topic. As such, this document contains a crosswalk to help readers track the changes.

IMPACT POINTS:

- **VERY SMALL** = UNOS complexity all departments
- 10 hours = Implementation all departments

Discussion: Project Size/Complexity

UNOS

Implementation and ongoing annual effort is minimal for all departments.

MEMBER

Hospital, OPO, Lab: No impact.

Histocompatibility Lab Policy and Bylaws Guidance

Executive Summary

The OPTN/UNOS Histocompatibility Committee created this guidance document in order to provide additional information or clarification for the OPTN/UNOS bylaws and policies. This guidance document is designed to assist members with interpreting the bylaws and policies governing histocompatibility laboratories and histocompatibility testing of donors and candidates.

This guidance document is intended only to provide guidance for labs on certain aspects of histocompatibility testing and written agreements. The guidance given for testing is not intended to overrule the clinical needs of a patient. Additionally, the scope and content of written agreements should reflect collaboration between laboratories and transplant programs, taking into consideration their needs and laboratory best practices.

IMPACT POINTS:

- **VERY SMALL** = UNOS project complexity all departments
- 10 hours = Implementation all departments
- 10 hours = Ongoing (annual) all departments
- Major implementation costs to labs not already following practice includes purchase of freezers and ongoing cost of supplies.
- Testing volume is major variable affecting ongoing cost.
- Hospitals and labs require joint staff time to develop crossmatching criteria.
- Guidance documents do not contain new member requirements. However the assumption in estimating fiscal impact is the members will follow guidelines.

Discussion: Project Size/Complexity

UNOS

Implementation requires minimal effort, attributed to Policy.

MEMBER

Lab: If members are not already following the guidelines, implementation and ongoing costs can be substantial. An additional storage freezer can cost up to $20,000. Supplies, including freezing medium, liquid nitrogen, reagents, allele typing kits, tubes, tube holders, and additional utilities can total to up to $50,000 annually, depending on testing volume. Minimal staff hours are required for training. If additional costs are not reimbursable or able to be absorbed by facility, labs can raise charges or create new charges to offset costs.

Most labs are likely already following the protocols outlined in the guidance, causing minimal fiscal impact.

Overall, additional costs vary widely, dependent on donor and waitlist testing volume and facility resources. Hospital labs may have access to additional shared resources, such as storage, while independent labs may have no shared resources.

Hospital: Additional joint lab and hospital staff time in developing virtual crossmatching criteria and recording sensitizing events for candidate is an implementation impact.

OPO: No impact.