

## **OPTN Executive Committee**

### **Meeting Minutes**

**June 14, 2021**

**Conference Call**

**David Mulligan, MD, Chair**

**Matthew Cooper, MD, Vice Chair**

### **Introduction**

The Committee met via teleconference June 14, 2021 to discuss the following agenda items:

1. COVID Policy Data Review
  - a. Repeal of Policy 3: Modify Wait Time Initiation for Non-Dialysis Kidney Candidates (
2. New OPTN Projects Recommended for Approval
3. Appendix L Bylaws Change
4. Liver & Intestinal Committee Charge
5. Update on OMB Data Collection Requirements

The following is a summary of the Committee's discussions.

#### **1. COVID Policy Data Review**

A member of the UNOS research department presented a data review of OPTN COVID-19 policies. She began by looking at the status of each of the five policies, including when they were adopted, whether they have been implemented, and when they expire.

Policy 1 was repealed in April 2021, effective July 2021. Policy 2 was repealed in March 2021, with forms due by July 1, 2021. Policy 3 is implemented and still active. Policy 4 is permanent and policy 5 became effective May 27, 2021, is implemented, and is scheduled to expire May 27, 2022.

Starting July 2021, only the active policies 1 and 3 will be monitored. As policies are repealed, the monitoring plan will be updated to reflect those changes. Monitoring of policy 5 will become available toward the end of July 2021.

Policy 1 focuses on updating candidate data during the COVID-19 pandemic. This policy currently sees very low use, with no adult heart candidates having used it in 2021 and only five adult heart candidates having used the policy since its inception.

Policy 4 is related to COVID-19 infectious disease testing data and trends and is currently permanent. Over 99% of donors recovered since February 2021 have COVID-19 results indicated in the discrete infectious disease testing fields, indicating that the community is actively using and sharing this data. Since April 2020, over 90% of all donors had lab results reported in the discrete infectious disease testing fields.

A total of 176 positive COVID-19 test results have been reported for 128 unique donors. In all cases, these positive results were communicated to transplant centers or made available to DonorNet prior to transplant.

Policy 2 on relaxing data submission requirements for follow-up forms was repealed in March 2021, with forms from the pandemic due July 1, 2021. As of June 7, 2021, the percent of forms expected is about 2% or less for LDF, PTM, and TRF forms.

Looking by organ and by week at the percent of matches with at least one COVID-19-related refusal reason, the numbers continue to stay generally below 20% and closer to 10% for some organs and weeks. The majority of refusals this year have been donor-related, compared with last year when the reasons had more to do with reports of other factors such as the logistics of transplant centers.

COVID-19 related deaths as a proportion of waitlist deaths by organ and week show that post-transplant deaths are still mostly among kidney recipients, although there is a decline in reported deaths since the end of January 2021.

#### Modify Wait Time Initiation for Non-Dialysis Kidney Candidates (Action Item)

The Executive Committee was provided with a review of the monitoring data for policy 3 in order for them to consider whether the policy should continue and when to resume standard listing requirements for non-dialysis kidney patients. The Committee was reminded that the policy allows programs to request waiting time modification for non-dialysis kidney candidates who meet waiting time accrual criteria by GFR or CrCl, but are unable to obtain additional labs required for listing.

The data show that non-dialysis kidney waitlist additions with no dialysis and a CrCl/GFR less than or equal to 20 at listing have for months consistently hovered around a third of total modifications to wait time initiation for non-dialysis kidney candidates.

In terms of the current utilization of policy 3, in May 2021 just over 63% of the waiting time modification requests submitted to the organ center were COVID-19 related. As of June 1, the policy has been used by 15% of all kidney programs since its inception.

A manager from the UNOS policy and community relations department then presented feedback from the Kidney Committee and briefed the Executive Committee on some outreach to the community.

The Kidney Committee reports that although the policy has had a large positive impact, they have not identified current COVID-related barriers to listing non-dialysis kidney candidates. Accordingly, there is a question around the need for this policy in the current stage of the pandemic. The Kidney Committee also discussed the timeframe for repeal and recommended a minimum of six weeks' notice for both the current use and the submission of all outstanding waiting time modifications. This was discussed during their May meeting and they then confirmed the approach with Kidney leadership following the June report release. In short, from the perspective of the Kidney Committee, this policy is not needed at this point.

In terms of program outreach, UNOS staff contacted the five programs with the highest usage of this emergency action. These programs accounted for over half of all wait time modification requests. Of the 37 centers that used the policy, 26 used it less than 10 times and 13 used it only once.

The centers reported that they incorporated the policy into their processes, but they explained that they do not see a need to continue the policy if COVID-19 case numbers remain stable. The program with the highest use stopped applying this process in October, but still has a few patients to list and apply for waiting time modification.

A committee member noted that it sounds like the Kidney Committee and members of the community have spoken and the policy is probably unnecessary at this time. He added that as a kidney transplant surgeon, he and his team continue to find ways through visiting nurses, outside labs, etc. to keep people from having to come to the hospital and to maintain their status on the waiting list. They've figured out

21<sup>st</sup>-century ways to get labs that don't entail people having to put themselves in vulnerable situations. He concluded that the OPTN could repeal this policy.

Another committee member agreed with what has been said, but thought that the six-week timeline was shorter than has been done with a lot of the other policies. She wondered whether input from staff was needed to see if that was realistic after they looked at the data or whether 90 days should be considered, as has been done with other policies. The Chair of the Executive Committee noted that there is some discussion on whether September 1 would be the ideal time to make this transition.

The presenter from the UNOS policy and community relations department noted that the kidney centers recommended at least six weeks to plan for this, but didn't oppose a longer period. From a staff perspective, they are supportive of September 1. Staff noted it is hard to anticipate how much time is needed and he agreed that too little advance notice would be detrimental. In addition, a lot of proposals that are approved at the June board meeting are implemented on September 1, barring some urgency to do it sooner. This period is necessary to make sure the community has enough time in advance and that communication and implementation efforts can be coordinated with other activities. These factors support a staff recommendation of September 1.

There was a motion and a second to repeal policy 3 effective September 1, 2021.

The vote was 100% yes; 0 no; 0 abstained

## **2. New OPTN Projects Recommended for Approval (Action Item)**

The Chair of the Policy Oversight Committee (POC) presented six new committee projects recommended for approval. She began by noting that one project that came out of the VCA Committee on updating VCA policies and data collection was sent back to the VCA Committee with suggested feedback to unbundle some parts of the project to reduce the resource pool. It will come back to the POC once it has been revised.

New Project 1 looks to evaluate living donor exclusion criteria in order to determine whether the current exclusion criteria are appropriate. After analysis, the POC supported the project. While the Living Donor Committee has other projects, it has the bandwidth to take on this new project.

Project 2 establishes a minimum set of donor kidney criteria related to biopsy. The goal is to establish clinical criteria for when an OPO must biopsy a donor kidney at a transplant center's request. The POC analysis supported the plan and timing. Although the Kidney Committee is busy with several projects, this new project fits within the sequencing of other efficient matching work.

Project 3 is being paired with Project 2 and came out of a POC direction for the strategic priorities for efficient matching identified by the work group, based on an idea from the Systems Performance Committee. Although different, projects 2 and 3 are similar in that they seek to create more standardized practices nationwide. The projects should be sequenced at the same time with the Kidney Committee and have been identified as a priority for the system, especially in light of broader distribution being in place.

Project 4 came out of the Ethics Committee and looks at transparency in transplant program selection through an ethical analysis on access to the waitlist. The POC felt this project was important, but that it should be phase one of a larger project that would involve the Data Advisory Committee. As a result, while the POC recommends approval of the project, they articulated that they want this to be phase one of a larger project that would roll in what the necessary data collection might look like. The POC is recommending that the ethics component will produce an analysis that will then be used by the DAC, PAC, and the MAC in the larger project. The DAC, PAC and MAC are on board with this work and the POC

expects a new project proposal coming from them in the near future. The Ethics Committee has the bandwidth to do project 4.

Project 5 came from the Histocompatibility Committee and looks to update the HLA equivalency tables to align HLA data in policy and UNet with current practices. It fits within existing Histocompatibility Committee work.

Project 6 seeks to modify the heart policy for pediatric candidates and intended blood group incompatible offers. It seeks to update policy to align with current findings in the field around ABOi incompatibility in pediatric heart transplantation. The goal is to increase the donor pool and potentially reduce the wait time. The POC supports the project. Although the Heart Committee has a fair amount of other work going on, this project would extend beyond their current work. The Pediatric Committee has the bandwidth to take on this work.

The Executive Committee was then given a snapshot of the project portfolio, including how well the new projects fit with current projects in the overall current strategic plan alignment. In terms of resource estimates, several of the new projects are relatively small and will not draw much resource time. The largest is the HLA equivalency table update for 2021, but the POC feels that that is needed work.

A Committee member thanked the POC because it is very valuable to get a look at this work in advance so the Committee can focus on upcoming projects. He found the slides of the timelines of the committee projects helpful and asked to see the slides regularly.

The POC Chair responded that the POC does do that for each committee and that could be provided to the Executive Committee. In addition, the POC has recently implemented an expectation that when a new project is approved, it will hit the next stage of policy development within 12 months. If it does not, the POC needs to understand why. If there is no rationale, the Committee would then take a fresh look at the project. The POC has worked hard to sequence work in a way that makes sense and does not want to approve a large project that doesn't move forward in the way they anticipated. They don't want to assume it's of the same value if it hasn't progressed 12 months later.

There was a motion and a second to approve the committee projects from the Policy Oversight Committee.

The vote was 100% yes; 0 no; 0 abstained.

### **3. Appendix L Bylaws Change (Action Item)**

The UNOS Policy Development Lead reviewed a technical correction to the 2017 revisions to the pediatric emergency membership exception pathway. She began by specifying that the Executive Committee was being asked to recommend it for consideration to the full Board of Directors because it is a bylaw change.

In December 2015, the Board of Directors (BOD) approved a proposal that builds pediatric bylaws that contained a pathway with an application for a pediatric emergency membership exception through a prospective process. In December 2017, the BOD approved a change to the process that changed it from a prospective one to a retrospective review of whether the exception met conditions and qualified.

Both proposals were implemented in 2020, but there are still some references to the application outstanding. Because they are bylaws, a vote is needed to eliminate them.

The proposal asks to remove the moot language in Appendix L related to a denial of a request for a pediatric emergency membership exception. The bylaws currently provide an opportunity for an interview or hearing if the review of the exception results in a rejection of the application.

There was a motion and a second to recommend the proposal for the bylaw change to the full Board of Directors. See **Exhibit A**.

The vote was 100% yes; 0 no; 0 abstained.

#### **4. Liver & Intestinal Committee Charge**

The Chair of the Liver Committee briefed the Executive Committee on some discussions his committee has had about expanding the Liver Committee's charge to allow consideration of allocation for all liver disease patients, not just those waitlisted. Proponents of this change argue it is necessary to understand if organs are moving from areas where there is a higher burden of liver disease in the population, but where there is poor access to healthcare. Opponents express concern that access to healthcare and state decisions about Medicaid are beyond the scope of the Committee. Further, not all end stage liver disease therapies include transplant.

The Liver Committee Chair reviewed some relevant OPTN final rule citations, predominantly around allocation policies, but noted that the crux of the matter is that most of the affected individuals would predominantly be in places where there is less organ access, poorer healthcare, and lower socioeconomic status.

The questions that the Liver Committee would like the Executive Committee to consider are whether expansion of the liver charge to include consideration of overall ESLD burden of a population falls within the scope of the OPTN's authority? If so, how? Would this impact charges for other committees?

If a patient with end stage renal disease is eligible for dialysis, they automatically get Medicare coverage. In the kidney world, this makes it efficient to identify people with end stage renal disease. Referral for transplant can be a metric for performance for centers and entities. With end stage renal disease, if the patient is not eligible for commercial insurance or Medicare, the national insurance policy of Medicare picks them up. With end stage liver disease, by contrast, if you don't have commercial insurance or Medicare, the only place you can get picked up for insurance is Medicaid, which is state funded. The problem is that the funding of state Medicaid programs is quite variable. In many states, especially in the south, the payment is so poor that the patients who have Medicaid are not eligible to receive a liver transplant.

As a result, there are patients with end stage liver disease that would be eligible for a liver transplant except that they do not have financial coverage, which is quite variable across the country. For example, the uninsured population in Texas is 18%, which is ten times higher than those in New York or California. The ability of an uninsured cirrhosis patient in Texas to access a transplant is a fraction of what it would be in other states.

Once this was discussed in the liver community, it became apparent to the UNOS staff that this proposed metric would have to be applied to all the organs, which is why it is being considered by the Executive Committee.

An incoming Board member stated that he liked the idea of looking at populations because it provides an opportunity to look in a broader way at access. There is some overlap between some federal programs and the OPTN and then there's a fall-off in the middle. For example, before a kidney patient gets on dialysis, the OPTN knows little about them. This provides an opportunity to look at that. An incoming Board member noted that the OPTN needs to think about the national needs for all these diseases. On the other hand, he questioned how the organization would identify them and what the administrative burden would be of keeping track of all this.

The Executive Committee Chair wondered whether it would be best to start exploring from the aspect of the earlier discussion around the Ethics Committee looking into access to underserved patients with end stage organ issues. That might be a better approach before expanding the charge to the Liver/Intestinal Committee to consider end stage liver disease burden in a particular area as a part of the allocation. That seems a bit like putting the cart before the horse.

The Executive Committee Vice Chair asked for clarification on what the ask was in this discussion. The Liver Committee Chair responded that the proponents would say that if you're in a state with poor access, poor healthcare, and many patients with end stage liver disease, then those patients need to be counted and represented, especially under a system that is endorsing broader sharing. In their view, broader sharing removes organs from these places and these patients need to be counted because they need access to those organs. If you don't recognize that these patients are out there, then you can't fully understand the need for liver transplant in those particular areas.

The Executive Committee Vice Chair followed up by asking whether the goal was to count them for the purpose of potentially modifying the allocation system as it currently exists. The Liver Committee Chair replied that that was his understanding, because you have to start somewhere. If you don't understand the need for transplant in these areas, you can't understand the need to keep organs in those areas.

The POC Chair commented that from the POC perspective, the earlier comment about the cart before the horse is important. The issue of understanding candidacy access to the list needs to be unpacked before one jumps to "this has to be part of allocation policy." There are other ways to address access to candidacy and waitlists, but until there is an understanding of what that looks like, she feels it's premature to say we should incorporate these concepts into allocation policy. There is broad agreement that access to transplant is something that the community needs to get a better handle on from the candidacy of waitlisting perspective. The POC Chair recommended that the systematic way to approach this would be to have the Ethics Committee start the social determinants of health project and have MAC, PAC, and DAC look at metrics for all of the organs. If the charge is changed in one committee without a clear direction as to what that means in policy development, there will be an uncoordinated body of work and discussion going on. The POC Chair advocated that it would be better to first understand how disparities impact access to candidacy and transplant waitlists and then think about the appropriate policy response to address those disparities systemwide. She noted that that work has already started, but it should get clear support for it to move forward rapidly. Once there is a better understanding, the appropriate policies may or may not include allocation.

The Executive Committee Chair noted that an example of what the POC Chair was talking about is the African American Transplant Access Program at Northwestern. They reached into a community to determine the differences in that population with kidney and liver disease and address them in ways to improve their literacy and understanding, respect the differences in their families and access to care, to improve the trust, and to provide a pathway for more African Americans to access and be seen by the healthcare system. In two years, they've increased the number of patients listed by 18%.

A Committee member noted that the OPTN is a proponent of trying to get access for patients who have end stage liver disease. He continued that it's not a balanced situation from his perspective, however, in the sense that the social determinants of how you get access mean that you get less people listed with more disease burden, so those fewer people listed have higher access. You get a privileged class of people who get more, faster, than the other group. If, for example, in Texas 20% of people cannot get access at all, but their disease burden is high, the argument that they should therefore get more organs does not make sense to this Committee member. If they're listed, it makes sense; if they're not listed, the Committee member felt that they should not get preference based on the fact that there is a large amount of disease burden. It's more important to know the social determinants of getting on the list

than making allocation changes at the present time. Once one has a handle on that, it goes back to the programs and the states for why they are not getting as many organs. The system the states have for Medicaid, etc. is negatively impacting their ability to get people transplanted.

It was noted that there are financial barriers to becoming a recipient, but not to donating. That means many states have class and financial disparities between donors and recipients. A lot of the increased access to organs evident in the south is due, in the Liver Committee Chair's opinion, in large part to this exclusion reducing the demand for transplant while the supply is the same as or higher than other places.

A committee member asked whether this might be part of the charge that the MPSC has now for creating a dashboard of performance for OPOs and transplant programs. That could be something to think about rather than jumping right into allocation. A different Committee member felt that the problem with that is that you cannot control state rules. Another Committee member noted that there is nothing his hospitals can do for the patients with no insurance, so it would not be fair to hold the hospitals accountable for their inability to treat those patients due to the absence of funding (whereas they might have funding if they were residents of a different state). The Executive Committee Chair further noted that the patients have other burdens they have to deal with in order to make it on the list as a transplant candidate. For example, their comorbidities have to be managed and they need a social system to support them post-operatively. There is a lot that adds to this complexity.

An HRSA attendee clarified that HRSA's position is that OPTN policy-making authorities do not extend to patients with organ diseases who are not on transplant waiting lists. If the OPTN analyzed a situation and provided a justification as to why a proposed policy fell within their purview, that would need to be discussed on a case-by-case basis.

A Committee member thanked the HRSA attendee for clarifying that. She noted that there is a difference between looking at what OPTN has authority for and what they care about. OPTN would be disadvantaging some other people on other waiting lists if they allowed end stage organ disease to become a factor in allocation. End stage organ disease doesn't mean transplant candidacy. In addition, she pointed out that payment is important, but the idea that OPTN has any ability to affect payment for transplant is again outside their authority.

A Committee member responded by noting that in response the proponents would ask, "Why doesn't OPTN have that authority?" Or what would be the pathway to change that if it's not part of the regulations? A Committee member responded that at the board level, he thinks there are a few people who are proponents of that approach. It's hard from the opposite side to get an idea of what they're thinking. He continued that his thoughts have changed a little in that regard and that it's important to hear them out fully.

The POC Chair suggested first investigating access to transplant candidacy as something that OPTN cares about. Then second, OPTN could ask what is in their purview to do about that? If it's not in their purview currently, should it be? If the answer is yes, then in what way? Jumping straight to allocation doesn't make sense to a lot of people. Allocating an organ to somebody who is listed and has access does not increase the access for a person who never got listed. In the POC Chair's opinion, conflating the idea of access to transplant with allocation policy is ill-advised.

A HRSA attendee added that there are legal restrictions to what the OPTN can do. The law only provides certain authorities. Some things identified might require a change in the law.

The Liver Committee Chair stated that the Liver Committee needs the Board to make a determination about whether this is something they need to take into account as they deliberate about continuous

distribution. Should this be part of the portfolio of the Liver Committee? He added that the proponents would ask what their pathway forward would be to make these changes.

The Executive Committee Chair summarized the discussion by saying that, at least from the Executive Committee, it is not within the scope of the OPTN's authority to add the disease burden to consideration of patients with liver disease to allocation policy development and algorithms. Although the Executive Committee does care about access to healthcare and wants to learn more about how they can help patient populations suffering with organ disease, until patients are evaluated and listed, that is not the purview, role, and responsibility of the OPTN. In future, changes in the law would need to take place for OPTN to expand into the domain of what they can do for patients in terms of healthcare management, access to funding, and expanding access to patients with disease burden.

The HRSA representative expounded that the authority of OPTN is provided by law and regulation. If the OPTN identifies something they feel should be within its current authority, then HRSA can look at that and provide OPTN with an opinion. But OPTN needs evidence to back up its proposal.

An incoming Board member asked the HRSA representative what method OPTN should use if they identify an egregious problem that required other governmental action. The HRSA representative replied that the OPTN could make a statement to the secretary that they have identified something that needs significant action.

The Executive Committee Chair stated that in light of that, the next best thing would be to learn about and investigate these issues. Then they can unpack the need and deficits. He feels the most important thing OPTN can do is help patients who are appropriate candidates get to their transplant centers and get on a transplant list. There are things OPTN can do better in that regard.

The Vice Chair of the Executive Committee asked whether the Executive Committee was asking the Liver Committee Chair to take this back to the Liver Committee. The Liver Committee Chair replied that he understands that the answer is "no." He was here to represent the views that were pervasive on the Liver Committee. He said he can take it back to them and say that the ruling of the Executive Committee is that this is not under the purview of the Board. To pursue this further, they would need to pursue mechanisms outside UNOS and change regulations. The most direct way to fix this would be at the state level and improve Medicaid coverage.

The Vice Chair of the Executive Committee emphasized again that the OPTN and the Committee care, but there are places where their authority ends.

Another Committee member stated that the best message might be that the proponents should be on the committees working on the social determinants of access. They need to get the data because everyone is working on speculation (although there is some data). In general, OPTN needs to know what the roles of access are first before making allocations based on early thinking. That's probably the best way to sell it back to the Liver Committee. The Liver Committee Chair indicated that he was comfortable with that.

## **5. Update on OMB Data Collection Requirements**

A service owner manager from UNOS IT updated the Executive Committee on the Office of Management and Budget data collection requirements and related timelines.

Since the early 1990s, the membership application forms and TIEDI forms have been approved by the Office of Management and Budget (OMB). The purpose of the approvals is for OMB to allow the public to evaluate the burden impact of new or edited data collection. The 2019 OPTN contract required that all official OPTN data be collected on OMB-approved instruments by the end of the contract period. This



means all applications within the OPTN systems must go through the OMB approval process and any new data collection or changes to data collection also require OMB approval.

Membership and TIEDI applications were submitted as full systems and have been approved by OMB for some time. Moving forward, everything in TransNet, KPD, Patient Safety, DonorNet, and Waitlist will follow the same process. First, each system will be submitted for approval. Then, once approved, OPTN will submit new data collection and substantive data collection changes through the same process for additional approvals.

In 2021, OPTN will submit TransNet and KPD with a goal of having them approved by the end of 2021 or first quarter of 2022. In 2022, the organization will submit DonorNet and in 2023 they will submit Waitlist. By 2024, all OPTN systems should be approved.

This will require a process change on the definition of substantive changes. Due to a new interpretation of the definition of “substantive changes” to data collection, a new OMB process had to be put into place. Under this new process, every time a substantive change is made to an OMB-approved OPTN data collection system, the full OMB process must be completed. This process includes a 60-day Federal Register Notice to allow for public feedback on the burden, followed by a 30-day Federal Register Notice. Once OMB reviews the public comment, they may approve the data collection changes and OPTN can implement them.

This full OMB approval process will be necessary for every OPTN BOD project that includes a “substantive change” to data collection or the addition of new data collection.

The Executive Committee was then given an overview of how this new policy will affect the timelines of four projects (PHS Guidelines/HBV Data Collection, Modify Data Submission, Further Enhancements to the NLRB Liver Explant Form, and Refine Lung Data Fields).

This change will also impact upcoming projects that are in design and expected to go to the Board in December 2021, including Data Collection to Evaluate the Logistical Impact of Broader Distribution; HLA Equivalency Tables Update 2021; VCA Membership Requirements for Genitourinary Transplant Programs; PHS Data Collection—Donor Fields (DDR); and Reporting Immediate Graph Dysfunction in Heart Transplant Recipients.

In summary, the repercussions of this OMB change will include that this contract requirement will impact the OPTN’s ability to deliver as promised and the community can expect delays past the 12-month delivery commitments in some cases. In addition, some project releases will need to be separated, based on system impact and OMB needs. Finally, the OPTN will work with the community to help prepare for multiple releases when necessary.

A HRSA representative noted that the timelines represent the longest timeframe it might take for OMB approval. It’s possible the changes might be approved in a December/January timeframe for all of them. It is an annual process that will be triggered in the early part of the year with an initial notice to the public that the OPTN data collection process will be changing. Then a second notice will go out after the June meeting that will include all specific changes that were approved at the last December and June meetings. That material will then go forward to OMB for approval. Historically, the OPTN has had good response times from OMB.

The HRSA representative also noted that if the Board approves a data change that it deems critical, it can be processed separately as an emergency change once the systems are in place. His hope is that this will create some consistency for the system, particularly as it moves to a world of APIs and direct data transmission.

An Executive Committee member noted that the community appreciated that the OPTN had become more agile in getting new policies approved and implemented in a timely fashion. Now the timeline looks like projects will be delayed at least six months. She asked once the general components are approved, what's the most rapid turnaround possible through the OMB process?

The representative from HRSA replied that he assumed that the 12-month timeframe that OPTN has been operating under should be feasible, although he could not promise that. The assumption is that there will be a 12-month process from the December meeting, but the changes from the June meetings could be implemented more quickly. He also noted that once the data are approved by OMB, the expectation is that the system will be collecting those data. As a result, beginning system implementation cannot wait until the system is approved. The implementation needs to be ready to go. This adds a layer of complexity, but the HRSA representative does not expect it to change things dramatically.

The Executive Committee Chair shared his concern about what would happen if OMB were to kick something back? Would that mean OPTN would have to wait another 12 months? The HRSA representative replied that in the past, there has never been a significant delay to implementation coming from questions growing out of OMB's public comments process. At that point, OMB is not looking at the content or policy; the main assessment then is burden.

In conclusion, the service owner manager from UNOS IT noted that any time they do pre-programming with a risk of potential changes, it is a high-risk moment. Any changes need to occur not only in OPTN's systems, but also in their vendors' systems. Second, there is a challenge around community readiness. As soon as something is approved, OPTN needs to make sure the community has the training, space, and time they need to prepare their institutions.

The Executive Committee Chair adjourned the meeting.

## Attendance

- **Committee Members**

- David Mulligan, Chair
- Atsi Yoshida
- Jeff Orlovski
- Lisa Stocks
- Maryl Johnson
- Mindy Dison
- Matthew Cooper
- Medhat Askar
- Robert Goodman
- Valinda Jones
- Brian Shepard, OPTN Executive Director
- Cheryl Dammons (HRSA)
- Frank Holloman (HRSA)
- Christopher McLaughlin (HRSA)
- Shannon Dunne (HRSA)
- Shannon Taitt (HRSA)
- Jim Bowman (HRSA)

- **SRTR Staff**

- Jon Snyder
- Ajay Israni

- **UNOS Staff**

- Steve Harms
- Alex Tulchinsky
- Jason Livingston
- Maureen McBride
- David Klassen
- Lauren Motley
- Liz Robbins Callahan
- Rebecca Murdock
- Chelsea Haynes
- Susie Sprinson

- **Other Attendees**

- Alexandra Glazier, POC Chair
- Jerry McCauley, 2021-2022 OPTN Vice President
- Elizabeth Saindon, Office of the General Counsel, U.S. Department of Health & Human Services