

February 15, 2024

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Health Systems Bureau  
Health Resources and Services Administration  
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SENT VIA ELECTRONIC MAIL

Dear Dr. Nair,

Last week the OPTN Directors were notified that the RFPs for the first phase of HRSA's OPTN Modernization Initiative had been released. The Executive Committee reviewed the RFPs and met to determine exactly how HRSA seeks to provide support to the OPTN in the future. We expected answers to the questions we have been asking for months, and, unfortunately, we found that the RFPs have left us with even more questions.

Despite months of discussion about change and improvement to the OPTN coming soon, the RFPs for the transition contracts seem at their best, to be a solicitation for ideas and HRSA has proposed to UNOS an extension of the current contract for up to two years. That seems consistent with the fact that the RFPs are not final, but rather they are drafts intended to allow those who may bid more time to learn about the requirements. This is disappointing because we have been partnering with HRSA to prepare the transplant community to be active and excited participants in this process. The undefined nature of the RFPs dampens this enthusiasm and injects more doubt and uncertainty into our community at time when anxieties are already running high.

We directors are profoundly disappointed that the draft RFPs did not provide more insight into HRSA's vision for the future of the OPTN. The work of the OPTN is focused on caring for people with end-stage organ failure. These individuals are very ill and at the end of their life without an organ transplant. The healthcare professionals that engage in this work and the patients and donor families who volunteer their expertise take the OPTN's role in this life-saving mission very seriously. It was our hope that publication of the RFP would be the first step in creating our new future, but what was delivered was a draft RFP offering no specific plan to improve the system. Our future continues to be uncertain and as leaders of this network, it makes supporting our community that much more difficult.

HRSA says that the actions it is proposing are in response to "the community." We reject this. At this moment, there is no organization other than the OPTN that can speak for the entire community because its members represent all aspects of the community. For this reason, we believe the OPTN's feedback should be a priority to HRSA.

The OPTN Board is a collection of representatives reflecting diverse perspectives elected by the OPTN members. The RFPs describe the OPTN as a “...comprehensive network of transplant professionals and community members.” NOTA provides more specificity, by including in the OPTN all transplant centers, OPOs, histocompatibility labs, individuals with patient and donor experience, and various others. By these definitions, the OPTN is the transplant community. Through the OPTN Board’s day-to-day contact with the community, regional meetings, public comment periods, and more than 700 volunteers working within the OPTN committees, the Board hears the ideas and concerns of the members, and, therefore, the OPTN Board has its finger on the pulse of the OPTN community.

Collectively, the Executive Committee of the OPTN has developed a list of issues, concerns, and questions we believe must be addressed before the next iteration of the RFP is published. These issues fall into two categories that require urgent review and action by HRSA. Additionally, in the coming week we will provide feedback and questions from the entire OPTN Board of Directors.

While the issues we identify are a component of contracts to be issued, the contracts only deal with support. The focus of the Executive Committee is on OPTN structure and operations. We believe NOTA and the Final Rule make the OPTN primarily responsible for transplant policy and operations. HRSA’s role is to provide contractors to support the OPTN and not who the transplant community chooses to fulfill Board responsibilities. NOTA was explicitly designed to place oversight of the transplant system in the transplant community. The draft RFPs propose a plan to construct a Board of Directors in a manner that is not compliant with NOTA and envisions support and operations activities that we do not believe are consistent with the needs of the OPTN and, more importantly, the patients it serves.

The following issues require immediate, thoughtful consideration:

#### OPTN Board Independence

The OPTN is the result of NOTA and the Final Rule, and OPTN Bylaws were created under that authority. The Board Support RFP contemplates a special nominating committee structured by the new contractor leading to a special election of a new Board. The resulting effect on then current Board members would be termination of their role as directors prior to the end of the terms set by the Bylaws. It is our understanding that:

- Neither NOTA nor the Final Rule have an explicit mechanism for the Secretary to remove OPTN Board members.
- OPTN Bylaws do not currently allow for special elections; and
- OPTN Bylaws do not currently provide for the designation of a special nominating committee or obtaining public input on committee memberships and Board nominations.

In our view, establishing a nominating committee, obtaining public input, and removing current directors prior to the end of their terms as described in the RFP would require the OPTN Board to vote to amend the Bylaws. This would require the Board to vote for a nominating process that it may not believe to be in the best interest of the OPTN, and to vote for its own disbandment. A two-thirds vote of the Board is required by the Bylaws to enact these amendments. Then, the community members of the OPTN would need to approve the Bylaws changes and the early discharge of then current members of the Board of Directors. Therefore, for HRSA's plan to proceed as stated, the following questions need to be addressed a priori.

- Will the OPTN Board vote to approve bylaw amendments?
- Will OPTN members vote to approve bylaw amendments?

If the answer to either of these questions is no, we request an explanation of what authority HRSA would use to carry out this proposed plan.

Because the RFP calls for the special election to occur before analysis of current Board structure is to take place, presumably the special election will be to fill seats on the Board as currently structured. If that is true, it seems the sole purpose of a special election and replacement of Board members is to create "independence," which some observers equate with removing any director who has served as a director of UNOS. It is asserting that Board members are acting in the best interests of UNOS and not the OPTN.

We remind you that awarding the OPTN contract to UNOS, HRSA accepted that that the UNOS Board member would serve as the OPTN Board. In our experience, Board members are overwhelmingly motivated to serve out of a desire to serve the OPTN and to positively impact transplant policy for the benefit of patients. Any interest in serving on the UNOS Board comes only with a desire to serve the OPTN not the contractor. HRSA has played a role in creating this conflict and has been relying on us to steer the transplant community and HRSA in a new direction. This conflict was not created by any OPTN director. We are concerned that by taking the significant step of discharging the entire OPTN Board at once, all institutional memory of this highly complex system will be lost. The OPTN will have a president and other officers who have not previously served on the Board and have no understanding of its workings or why current policies are in place. We are concerned that a wedge will be created between HRSA and the OPTN community. In our opinion, that outcome would be disastrous for everyone but most importantly the patients we serve.

#### Board Restructure

We do acknowledge it may be appropriate to restructure the board composition, and we are open to those discussions. Many within the OPTN, including many current and former Board members, have discussed the difficulties of managing OPTN business with such a large Board. There is discussion amongst the OPTN Board of Directors as to whether the patient and donor community is adequately represented and what changes are needed to remedy this. Additionally, there may be better ways to assure diversity of views than by regional

representation. These and many other questions are appropriate and should be asked. It is necessary to point out that the current Board and those that preceded it, were constructed in accordance with requirements in NOTA and the Final Rule. The current Board of Directors fully supports change designed to improve the OPTN. However, any change must be well thought out, protect the well-being of patients the OPTN serves, and designed to ensure that the mission of the OPTN is carried out in a responsible manner. Therefore, the following questions need to be answered:

- Is it better for board replacement to occur before or after a full review of composition and process?
- Why would a special election take place before this work has been completed? Task Orders should be issued in sequence so these workstreams are not simultaneous processes.

#### Corporate Status of the OPTN and its effect on Board Separation

Although the exact status of the OPTN is made very uncertain in statute due to its unique structure, for nearly 40 years the directors of the contractor have served as the OPTN Board. These individuals have benefited from the protection against personal liability provided by the corporate structure of UNOS. Based on the contents of the draft RFP, it is not clear how HRSA intends to preserve these protections.

As we have previously discussed, the UNOS Board has amended the UNOS Bylaws to restructure the composition of the UNOS Board. As has been well documented, both the UNOS Board and the OPTN Board have been working to achieve an orderly separation for more than two years. Both UNOS and the OPTN Boards have called for the incorporation of the OPTN. Because of concerns expressed by HRSA, we do not believe this goal has been achieved. UNOS has done what was necessary to achieve board separation, as requested by HRSA, Members of Congress, the OPTN Board, and the UNOS Board. The effective date of this restructure is March 30, 2024, timed to match the expiration of the current contract, and with the expectation that HRSA would fulfill its responsibilities and adopt a plan for the post-March 29 structure of the OPTN. On February 8, 2024, HRSA notified UNOS of its desire to extend the current contract for up to two years, but so far HRSA has been silent on any plans to incorporate the OPTN.

When the requested separation of the UNOS Board from the OPTN Board takes place, the UNOS Board will no longer satisfy the requirements of the Final Rule for composition of the OPTN Board. For more than two years, both the OPTN and UNOS Boards have been requesting HRSA to incorporate the OPTN in anticipation of this change in the UNOS Board structure. At the request of HRSA, UNOS submitted a plan for Board independence, which included incorporation of the OPTN. The OPTN is a highly complex organization, with hundreds of individuals involved as volunteers, with more than 400 corporate and individual members and with highly varied responsibilities impacting the lives of more than 40,000 recipients annually and more than 100,000 on the waiting list. Throughout the United States, it is inconceivable that any such organization would not be structured as a corporation.

The OPTN Board appreciates the fact that UNOS has acted on its responsibility to serve the best interests of the OPTN. The Board notes that HRSA has never taken action on the contractor's proposed plan for OPTN Board independence or any of the other options that HRSA indicated it was considering. The implication was that HRSA desired to address this issue in the RFPs. However, the RFPs are silent on OPTN organization after board separation, and the current OPTN Board Requests immediate clarification on how this issue will be addressed now so it can move forward with the knowledge that board members will be protected.

It appears HRSA now seeks and expects the OPTN Board, and by extension the entire OPTN, to operate as an unincorporated association. Without being an incorporated entity, all board members, all volunteers, and all members are put at great risk. A business organization formed under specific state laws, such as those creating corporations and limited liability companies, protects those associated with the business from personal liability. An unincorporated business provides no such protection. Individuals, and business organizations who are members, are liable for the debts and obligations of the organization. The organization cannot hold property or enter into contracts. It is a non-entity for legal purposes.

Without a defined corporate structure, not only do all involved volunteers have personal risk, questions will be raised about the organization itself, how it is governed, how it operates, and by what authority it enforces policy. It will have bylaws, but if those bylaws are subject to arbitrary override by HRSA, are they bylaws in name only. The ability to enforce members' compliance with bylaws will be undermined. Corporate law provides a framework in which all who are within and without an organization understand the rights, duties, and relationships of various stakeholders. Similar questions among those involved with unincorporated associations remain subject to conjecture. If not resolved by agreement or the arbitrary use of power, they are ultimately resolved by our legal system. Is that HRSA's objective?

The use of the term "independent" is interesting. Some outside the community seem to equate independence with separation from the contractor. That will happen on March 30. However, the OPTN Board strongly feels that independence means free from the influence of the contractor and the ability to be a counter weight to governmental overreach when such actions, as we now experience, run counter to the best interests of the patients it exists to serve. The only way to accomplish true independence is to establish the OPTN as a separate entity, not simply a collection of individuals who are bound only by their interests in transplantation. If there is no entity, who is the beneficiary of the directors' duties of loyalty and care? There would be no actual OPTN. Who would be the beneficiary of confirmation by a director that the director has no conflict of interest? The OPTN would simply be a collection of individuals, each with their own objectives and needs.

How does the OPTN convert from a corporate structure within UNOS to a separate organization? Does that require a vote of OPTN members? What is the role of members? Are members required to apply for membership in an organization that is not an entity? And if not, how will policies be enforced? These are questions that must be addressed, and they can be easily answered with a corporate structure.

HRSA has proposed that D&O insurance can be obtained, but our preliminary inquiries indicate that may be problematic if the OPTN is not a corporation. Even if it is available, will the protection provided be equivalent to that provided by a combination of a corporate structure and insurance? We believe it will not. Will it cover committee leadership and members? Will D&O insurance protect OPTN members from claims made against the OPTN? Claims made against an unincorporated association are most likely initially made against the directors individually, because there will be no OPTN in existence, but creative lawyers find ways to sue everyone involved, and let the courts decide who is actually responsible. That puts individuals and corporate members at risk in ways that they would not be if the OPTN is a corporation.

NOTA was changed last summer so that it no longer requires that the OPTN be a private, not-for-profit entity. However, the Final Rule still requires that the OPTN be an entity and strongly implies that it will be a corporation. How will HSA reconcile this difference?

#### Who will volunteer for the new OPTN?

At our recent Executive Committee meeting, multiple current members of the Board have stated categorically that they will not serve on the Board if the OPTN is not incorporated. Other directors have indicated the likelihood that they will not serve. Since the issuance of the RFPs, multiple inquiries have been made by people who are currently candidates for election to the Board, asking questions about liability protection and suggesting the likelihood that they will not serve under the structure proposed by HRSA.

Volunteers populate all OPTN committees. They serve because they hope to help improve transplantation, to respond to needs as changes occur, and to help patients. However, any perception of personal risk as the result of actions they take is a significant disincentive. By way of example, if the allocation policy decisions of the Liver Committee and the Board were made at a time when everyone involved might have personal liability, how would the decision have been different and would have that been in the best interest of patients?

An organization is only as strong as its structure and documentation. A corporation has a long-term, if not indefinite, existence. It operates under the structure of state or federal law and within the charter and bylaws of the organization. Those who are members and those who are leaders know what to expect and what their various rights and duties are. None of these protections are present in an unincorporated association, especially if HRSA takes the position that it has the right to unseat a board or otherwise ignore OPTN Bylaws through contract or administrative action.

On behalf of the Executive Committee of the OPTN, we ask that you review and consider the above, and promptly respond to our interrogatives in writing within one week of receiving this letter. We also request that HRSA communicate directly with the OPTN Executive Committee of the Board of Directors on a private call to discuss meaningful solutions to these challenges. As volunteers, the OPTN Board has been tasked with safe and effective operations of the organ

donation and transplant system and protecting the patients it is responsible for serving. This role is taken seriously by each Board member. HRSA must remove any personal risk to Board members so that their decisions can be in the best interest to modernize the transplant system and not be stifled by fear of personal liability.

Sincerely,



Dianne LaPointe Rudow, President



Richard Formica, Vice President

CC: HRSA Contracting Office

CC: HRSA Administrator Carole Johnson

CC: HHS Secretary Xavier Becerra