

February 27, 2024

Naomi Inazawa, MSL
Contracting Office
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20852

SENT VIA ELECTRONIC MAIL

Dear Ms. Inazawa,

The OPTN Board of Directors appreciates the opportunity to ask questions regarding the OPTN Operations Transition (RFP 75R60224R00008) and OPTN Board Support (RFP 75R60224R00009) solicitations. After a thorough review of the draft RFPs and performance work statements, the Board submitted questions via the vendor question intake forms on February 27, 2024. A list of our questions is available as Appendix A.

Members of the OPTN Board of Directors engaged with HRSA during industry days, meetings, and throughout the stakeholder engagement phase of the OPTN Modernization Initiative. 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. We object to the idea that the OPTN Board of Directors is treated like a vendor, as opposed to the group that is responsible for the faithful execution of NOTA and the Final Rule. Looking forward to a productive future, we believe there needs to be a defined relationship between the OPTN Board and HRSA that fully articulates our mutual rights, obligations, and responsibilities in this partnership.

The Board remains committed to the OPTN, to the transplant community, and, most importantly, to caring for individuals with end stage organ failure. The Board seeks answers to our questions to ensure that HRSA is successful in their transition and maintains its commitment to guarding against interruptions in the systems and functions that support the OPTN.

Sincerely,



Dianne LaPointe Rudow, President



Richard Formica, Vice President

CC: Suma Nair, Frank Holloman, Chris McLaughlin

CC: Gina Dillon, Jimmy Hupalar, Shirley Karver, Jun Ji, Bonnie Garcia

Appendix A: Questions Submitted via Vendor Questions Intake Form on February 27, 2024

1. We believe the OPTN needs to be a fully independent non-profit corporation, with the ability to carry out the instructions of the Final Rule, procure directors and officers insurance, obtain and manage a bank account, retain legal counsel, hire and compensate staff. The OPTN Board needs to know HRSA's plan to establish such a corporation. When will this be forthcoming?
2. As per the Final Rule, members are responsible for payment of fees to the OPTN. How will this be achieved without the OPTN being an independent legal entity? How will the vendors be paid?
3. Who employs and pays the Executive Director and any associated staff? Will they be employed directly by the OPTN Board of Directors, or will they be employed by the contractor who holds the Board Support contract? Is the role of Executive Director a full-time job/devoted function? The OPTN Board appoints the Executive Director (per the Final Rule).
4. HRSA has stated that they are committed to providing insurance for volunteers. What is the status of this? How will volunteers be protected? Can HRSA provide assurances that routinely used Directors & Officers (D&O) insurance is sufficient to safeguard OPTN Board members? We do not believe this is sufficient for the OPTN, please explain your rationale.
5. Please explain why the OPTN Board is not permitted to use contract funds to obtain independent legal consultation.
6. HRSA's stated goal is to have multiple different "best in class" vendors. What is the workforce plan to manage multiple contractors?
7. How will funding flow between contractors? Who will oversee the collection, management, and distribution of funds? Who will resolve conflicts between contractors regarding resource allocation?
8. Who oversees the differential distribution of registration fees and federally appropriated dollars?
9. Will all contracts be jointly funded by registration fees and appropriations, or will some contracts be funded exclusively by appropriations, while others are funded exclusively by registration fees?
10. How will HRSA partner with the OPTN Board to set registration fees that allow for the continuous operation and enhancement of the OPTN?
11. How can HRSA help ensure effective collaboration among the OPTN Board, HRSA, and multiple contractors in a way that builds trust among all parties and respects the volunteer nature of the OPTN Board member role?
12. What role will the Board play in effectively facilitating relationships between contractors and providing oversight? How are long- and short-term priorities determined?

13. If the Board support contractor will be asked to review Board composition and nomination processes, why would the special election take place before this work has been completed? The tasks could be adjusted so they are not simultaneous processes.
14. NOTA, the Final Rule, and the OPTN Bylaws do not contemplate special elections or Board member removal (without an action of the existing Board). How does HRSA plan to achieve this?
15. Which of the current committees are Board committees, and which are not? Which contractor will support each group of committees? Please explain your rationale.
16. The OPTN will be independent of both the contractor and HRSA. Will the Board support contractor have their own researchers, statisticians, lawyers, policy analysts, accountants? Or will they rely on other contractors for these functions? If resources will be shared, who will oversee the effective use of such resources?
17. We believe the OPTN Board should have a role in responding to feedback for items identified in the transformation domain. What is the role of the OPTN Board in the transformation domain?
18. The OPTN Executive Committee noted a theme of redundancy and duplicative effort of checking the work of multiple contractors (Task 4 #s 6, 7, 8, 9, and 10). What oversight responsibilities will the OPTN Board have?
19. We believe that removing OMB approval from the contract is critical to the efficient managements of the OPTN. Will HRSA commit to removing this requirement?
20. L.4.2.4 Technical Factors for Domain 4, Communications: based on findings in the NASEM report, a patient portal should be required in module 4 so that patients have a centralized source to see if they are listed, what status they are listed as, and what institution they are listed with. Will HRSA commit to including a patient portal in module 4 of the operations contract?
21. We believe the OPTN Board should have a role in making decisions regarding Board composition. How will the OPTN Board be engaged in making decisions about future Board composition?
22. We believe the OPTN Board should have a role in making decisions regarding changes to the Final Rule. Task Area 2, #4 states that the OPTN Board Support contractor will "Support HRSA in developing materials to update the OPTN Final Rule as necessary". How will the OPTN Board be engaged in pursuing changes to the Final Rule?
23. For the Next Gen contracts, the OPTN Board must be involved with RFP development, vendor selection, and how task orders are issued. How will this be accomplished?
24. How will the OPTN Board execute oversight of future contracts? For example, tasks reference HRSA *and* the OPTN approving different communications. How will responsibilities be divided? How will HRSA eliminate barriers between the OPTN Board and execution of its oversight tasks?
25. What formalized mechanism will be created to allow the OPTN Board to provide HRSA with feedback on contractor performance?
26. What is HRSA's short-term transition plan for the OPTN after March 29? Is there funding for this transition plan? Will new awards be made while a potential extension/bridge contract with the current contractor is in place?

27. If OPTN Board legal protections through the formation of a corporate entity are not finalized, what contingency plans are in place to ensure smooth operations of the OPTN on March 30?