



ASTS Questions Related to OPTN Modernization

Industry Day – July 21, 2023

- Under the PWS, as currently drafted, will a contractor be able to bid on just a single “Task Area”? If so, would it be correct to conclude that there could be up to six contractors? If not, how many “Task Areas” will a contractor need to include in its bid?
- If it turns out that there will be more than one contractor, which contractor (or other entity) will have the responsibility to coordinate the services provided by the different contractors? What is the anticipated process for ensuring that such coordination occurs expeditiously and without the need to resort to HRSA mediation?
- What qualifications will be required for those interested in bidding to provide the services specified under the PWS? Will different qualifications be required for the different Tasks?
- Will specific performance or other criteria be established for each of the Tasks specified in the PWS?
- ‘The “Securing the U.S. Organ Procurement and Transplantation Network Act”, which is strongly supported by HRSA, *mandates* an organizational structure under which the OPTN Board, which will establish OPTN policy, will be entirely independent of the HRSA contractors, which will operate the system.
 - The PWS suggests that the Board entity will have no employees or other staff (with the possible exception of the Executive Director), independent of the staff provided by HRSA contractors. Is this a correct interpretation of the PWS?
 - Under this structure, will the Board entity be considered the “OPTN”? Will member dues and Registration fees be paid to the Board entity? If so, will the Board entity pay some or all of the funds to HRSA contractors, such that these contractors will be paid both by the Board entity and by HRSA? If so, will the Board entity have power to terminate an underperforming contractor?
 - If not, what power, if any, will the Board entity have to ensure timely implementation of the policies it approves, appropriate interpretation of its policies or otherwise ensure that the policies it approves are executed expeditiously and appropriately? If the Board effectively has no or limited authority to direct the activities of the contractor(s), what entity will be ultimately responsible for OPTN operations? In other words, where does the “buck stop”?



- Will the contractor(s) be directly responsible to the Board, to HRSA, or to both? If both, what happens if HRSA does not agree with a policy approved by the Board?
- The OPTN Final Rule requires that the OPTN be a non-profit organization and sets forth specific requirements with respect to Board composition and OPTN responsibilities.
 - Does HRSA intend to modify the Final Rule in conjunction with the modernization initiative? If so, when?
 - Is it anticipated that the OPTN Board composition will remain unchanged during the transition? After the transition? Who decides on the size and composition of the Board entity?
- We understand that HRSA has informed UNOS that the current contract may be extended for six months (i.e. through March 31, 2024), but that it will not be extended beyond that point. Is this a correct understanding of HRSA's plans?
 - If so, how and by which entity will the functions currently performed by UNET be performed on April 1? Is it anticipated that a "transition contractor" will operate UNET during the transition period (i.e. after April 1)? Regardless of whether the current contractor or a transition contractor operates UNET during the transition period, will there be a testing period during which UNET and any new IT system will be run in parallel?
 - Likewise, is it anticipated that the "transition contractor(s)" will staff the OPTN Policy and other Committees, maintain the current OPTN data systems, and otherwise replace UNOS staff beginning on April 1?
 - How, when, and by whom will transition contractor staff be trained to take over the IT and non-IT tasks currently performed by the current contractor?
- The PWS anticipates that the contract(s) will have one year terms, which will be renewable for subsequent one year terms. Many OPTN projects require multi-year investments of time, money and personnel. Will one year terms provide contractors sufficient incentive to make the investments necessary for the OPTN to carry out its complex multi-year functions?