

ASTS Questions Related to OPTN Modernization

- 'The "Securing the U.S. Organ Procurement and Transplantation Network Act", which is strongly supported by HRSA, would appear to mandate 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. Is this a correct understanding of this legislation?

Yes       No

- It is our understanding that, under the proposed new structure, the OPTN/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 understanding of HRSA's plan?

Yes       No

- It is our understanding that, under the proposed restructuring, patient registration fees will continue to be paid to the OPTN / Board entity). Is this a correct understanding of HRSA's plan?

Yes       No

- If the answer to this question is "yes," will the OPTN be responsible for paying for some or all of the cost of the services provided by the Next Gen contractor(s), using the patient registration fees?

Yes       No

- Regardless of whether the OPTN/Board entity will be responsible for the payment of the Next Gen contractors, will the OPTN/Board entity have a role in choosing the Next Gen contractors?

Yes       No

- Will the OPTN/Board entity have the authority to terminate an underperforming contractor?

Yes       No

- Will the composition of the current OPTN Board continue unchanged during the transition period?

Yes       No

- Will it be possible to reduce the size of the Board of Directors when the OPTN is established as an "independent entity"?

Yes       No

***[Please note that while both NOTA<sup>1</sup> and the Final Rule<sup>2</sup> include provisions that impose requirements with respect to the composition of the Board, these requirements could be met with a significantly smaller Board of Directors. For example, a Board of Directors of 18, consisting of 9 physician/surgeon; 4 donor/recipient/candidates and family members; and five representatives of OPOs, transplant hospitals, voluntary health associations and the general public would meet the statutory and regulatory requirements. ]***

- Does HRSA plan to propose modification of the Final Rule?

Yes  No

- 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?

Yes  No

- Will DonorNet continue to operate during the transition?

Yes  No

- If yes, will the Transition Contractor(s) operate DonorNet during the transition?

Yes  No

- If yes, will there be a training period during which the current contractor's staff will be available to assist and answer technical questions regarding the system?

Yes  No

- More generally, does HRSA plan to contract with the current contractor staff to help train or answer questions of the transition contractor(s) regarding OPTN operations, IT, communications, member oversight or other task areas?

Yes  No

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<sup>1</sup> NOTA requires that the OPTN Board include:

representatives of organ procurement organizations ...transplant centers, voluntary health associations, and the general public.

NOTA, Section 274(b)(1)(B)(i).

<sup>2</sup> The Final Rule requires that approximately 50% of the OPTN Board consist of physicians or surgeons, that 25% consist of transplant candidates, transplant recipients, organ donors and family members; and that 25% consist of representatives of OPOs, transplant hospitals, voluntary health associations, transplant coordinators, histocompatibility experts, non-physician transplant professionals, and the general public. 121 CFR § 121.3(a)(1)