



**OPTN Modernization and Reform Initiative Update
Published July 2024**

OPTN Modernization & Reform

As you may be aware, the AST has established a regular cadence of meetings with HRSA, Capitol Hill, the patient community and other key stakeholders regarding the OPTN Modernization Initiative. These strategic interactions with our Society's leadership have included recent meetings with the Senate Finance Committee, House of Representative's leadership and the Associate Administrator of HRSA, before during and after the recent ATC meeting in Philadelphia.

Please see below the recent update to the Society's membership outlining the AST activities and strategy in this arena:

Dear Colleague,

I write to you today regarding the Organ Procurement and Transplantation Network (OPTN) reform and modernization initiative currently being implemented by the U.S. Department of Health & Human Services (HHS) Health Resources & Services Administration (HRSA). As you know, this federal oversight initiative has a variety of implications for the field of solid organ transplantation and the important patient population that we serve. For those of you that attended the recent American Transplant Congress (ATC) in Philadelphia, you know that this regulatory oversight topic was front-of-mind for all involved, including patients, families, physicians, and the entire transplant community broadly defined. There is no question that the topic of OPTN reform and modernization has generated passionate discussion, debate, and strong feelings from within our community as well as outside external stakeholders. As such, I want to take this opportunity to provide an update of past, present, and future actions taken by the

American Society of Transplantation (AST) to impact and lead during this time of reform and modernization.

AST Strategic Approach

Let me be clear that the AST leadership has remained close and fully engaged with HHS HRSA, Capitol Hill, the patient community, and within our own ranks throughout the entire process of OPTN modernization and reform. The Board of Directors, Executive Committee, and our OPTN Modernization Task Force have worked on an almost daily basis responding to and educating key decision-makers as this process has evolved. As in the past, AST leaders have sought a thoughtful and collaborative approach to ensure a strong voice and seat-at-the table for shaping OPTN modernization now and in the future.

Society Engagement

AST has worked collaboratively with all stakeholders from the transplant community, the Administration, and Congress since the OPTN modernization and reform initiative was first initiated at the legislative and regulatory branch implementation levels. Some of these activities include (but not limited to) ongoing robust dialogue with:

- OPTN Leadership
- Patient Community
- Stakeholder Organizations
- Capitol Hill
- HHS HRSA
- Centers for Medicare and Medicaid Services (CMS)

During these discussions we have strongly advocated for transparency in the reform process and increased ongoing communication so that we and the entire transplant community remain well informed of anticipated changes and timelines. In addition, we will continue to represent those disadvantaged groups (minorities, children, specific disease groups among others) in our efforts for this reform. We are committed to championing that access to transplant for all patients is not negatively impacted by any of these changes.

Leadership & Being Part of the Solution Moving Forward

As we move forward, rest assured that the AST will continue to thoughtfully navigate the OPTN reform and modernization initiative with a strong focus on protecting and serving the reason we are all here-our patients. And please do not be confused regarding the Society's thoughtful and deliberate policy strategy. This collaborative and proactive approach has served the AST well in advancing our legislative and regulatory priorities for many years. Finally, we do ask our AST members to confer with leadership when representing the AST in OPTN Modernization discussions to be consistent with our society views.

I look forward to continuing to provide you with regular OPTN reform and modernization policy updates. In the interim, please do not hesitate to reach out to me via our [AST Public Policy Form](#) with your concerns or ideas.

Sincerely,

Jon Kobashigawa, MD

AST President

OPTN Modernization & AST Engagement With HHS, HRSA, CMS, OPTN and Stakeholder Community

AST leadership met with HRSA Associate Administrator Dr. Suma Nair during ATC as well as the last week of June. Society leaders also met with the U.S. Senate Finance Committee the first week of July. Additional meetings are on the books for later in July as well.

Background & History

AST leaders continue to meet with HHS leadership and HRSA Associate Administrator, Dr. Suma Nair as well as her organ transplant policy team. The Society has established a regular cadence for ongoing dialogue with Agency leaders as the modernization process continues to evolve. Since that time, the Society has continued to engage Congress and HHS as the OPTN Modernization & Reform initiative advances. AST recently met with OPTN leadership and is meeting with the HRSA Associate Administrator and Division on Transplantation (DoT) next week at ATC in Philadelphia. Society leaders will also be meeting with various targeted HHS officials during the upcoming annual meeting.

Most recently, on May 3, 2024, after soliciting and reviewing public feedback following the release of draft requests for proposals in February 2024, HRSA issued final requests for proposals to support multiple contract awards. As stated by the Agency, “this is a key step in the OPTN Modernization Initiative to improve transparency, performance, governance, and efficiency of the US transplant system to benefit patients and their families. This action will increase competition ensuring patients and their families benefit from best-in-class vendors.”

See HRSA’s [OPTN Modernization webpage](#), for more information.