

The September 2019 Omnibus Burden Reduction Final Rule: A Summary for the SATA Community

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In September 2019, the Centers for Medicare & Medicaid Services (CMS) released the Omnibus Burden Reduction Final Rule to “reduce unnecessary burden for American’s healthcare providers allowing them to focus on their priority – patients.” To better understand how this will affect the transplantation community, I interviewed two transplant surgeons on the American Society of Transplant Surgeons (ASTS) Legislative and Regulatory Committee, Drs. Kenneth Andreoni and Anil Paramesh. Dr. Andreoni is the chief of the division of transplantation surgery at the University of Florida College of Medicine and a former United Network for Organ Sharing (UNOS) president (2013-2014). Dr. Paramesh is the director of kidney/pancreas/living donor transplantation at Tulane Hospital, has held many advisory roles within UNOS and the ESRD network, and is the current co-chair of the ASTS Legislative and Regulatory Committee.

Before discussing the implications of the new ruling, it is useful to understand more about the regulatory structure. There are two separate regulatory agencies under the US Department of Health and Human Services (HHS): the Health Resources and Services Administration (HRSA) and CMS. The National Organ Transplant Act, passed in 1984, made the sale of human organs illegal and led to the creation of Organ Procurement Organizations (OPOs) and the Organ Procurement and Transplantation Network (OPTN). The OPTN both collects data from and oversees the transplant centers and OPOs. Every 7 years, a contract is released by the OPTN, and thus far has been awarded to UNOS. Additional legislation in 1987 established the Scientific Registry of Transplant Recipients (SRTR) to analyze the data from the OPTN/OPOs. The OPTN is the clinical arm of HRSA, and the SRTR is the statistical arm. The Membership Professional Standards Committee (MPSC) is a committee of the OPTN Board of Directors that oversees the outcomes and safety of transplant programs. The MPSC outcome regulations are guided by data from the SRTR.

For decades, it has been argued that CMS and OPTN impose redundant regulations. Every 6 months, both CMS and OPTN/MPSC release their assessments using the same data with differing statistical tools. Over the average three-year period, nearly a third of programs are flagged for low performance. Centers that were flagged twice by CMS were at risk of losing Medicare funding and being shut down. As CMS is the largest payer for transplantation, these low performance evaluations led to programs becoming more conservative and avoiding sicker patients with a resultant decrease in transplantation rates. With the Omnibus Burden Reduction Final Rule, CMS has eliminated the redundant outcomes oversight and duplicative paperwork. They will still continue to be involved in Quality Assurance and Performance Improvement (QAPI) and will investigate complaints, however they will no longer flag the low performing programs based on one-year outcomes. While this is the first big step toward the modernization of assessment of transplant programs and decreases regulatory burden, there is still stringent oversight from the OPTN/MPSC. Currently, more programs are being flagged by the MPSC than CMS. Furthermore, the SRTR implemented a 5-tier ranking system, which has disincentivized risk taking as centers need nearly perfect results to achieve the top tier. Studies have shown that the difference between 4 and 5 stars may just be a few percentage points.

The most important goal is to increase transplantation, and the most direct way to do this is to increase the donor pool. With a decrease in restrictions, centers will be more willing to take chances on higher risk donors and recipients. Outcome measures should be clinically relevant, so while graft and patient survival rates may be 1-2% lower at one center compared to another, these values should be compared to the

best medical outcomes to determine clinical significance. Additionally, it is difficult to accurately identify low performing centers, with false positives promoting risk-averse practices. We must develop better risk-adjustment models to more precisely evaluate candidate and donor risk. We commend CMS on taking this first step and hope that OPTN/MPSC will follow their lead so that we may offer the life-saving opportunity of transplantation to more patients. It is unlikely that we will see major shifts in our transplant patient population until both HRSA and CMS meaningfully decrease the regulatory burden.

For further details, I highly recommend the two articles referenced below.

1. Andreoni KA. Now is the time for the Organ Procurement and Transplantation Network to change regulatory policy to effectively increase transplantation in the United States; Carpe Diem. *Am J Transplant*. December 2019. <http://www.ncbi.nlm.nih.gov/pubmed/31883214>.
2. Jay C, Schold JD. Measuring transplant center performance: The goals are not controversial but the methods and consequences can be. *Curr Transplant reports*. 2017;4(1):52-58. <http://www.ncbi.nlm.nih.gov/pubmed/28966901>.

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