

February 4, 2020

The Honorable Alex M. Azar, II
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RE: Optimizing the Care of Americans with End Stage Renal Disease (ESRD)

Dear Secretary Azar et al:

On behalf of the American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS), we request your assistance and offer our expertise in determining methods to improve the care of patients with kidney failure. The AST is an organization of more than 4,000 transplant professionals dedicated to advancing the field of transplantation and improving patient care by promoting research, education, advocacy, organ donation, and service to the community. The ASTS is a medical specialty society representing approximately 1,900 professionals dedicated to excellence in transplantation surgery. The mission of ASTS is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

The Joint AST/ASTS Metrics Taskforce was established to complete a comprehensive assessment of the US kidney transplant system. We are convinced it is time to develop quality

metrics that encompass the whole of organ transplantation and that will benefit people with kidney disease, who are optimally treated by organ transplantation. In this light, we feel that a dialogue between patients, providers and administrators/regulators is critical for system change. We have concluded that a system-wide, disease-based approach to transplant quality metrics is the best way to assess the donation/transplantation system. To that end, we think the system to measure transplantation should be directly beneficial to those needing a new organ.

The Joint AST/ASTS Metrics Taskforce recently published an article in the American Journal of Transplantation¹. The article makes the case for reform of transplant center metrics. Over the last 20 years, transplant recipient outcomes have improved and differences between transplant program performance has decreased, making 1-year graft and patient survival poor measures of the quality of a transplant program. These metrics have had a pernicious effect on the utilization rates of donor kidneys. Transplant centers are disincentivized to utilize organs that are non-ideal, and to “cherry pick” patients, while competing for these artificial ratings. Additionally, the current metrics have had the unintended consequence of stifling innovation. With the release of the CMS Conditions for Coverage (CfC) revised OPO performance metrics, we perceive that the process should be hastened and incorporate our concerns relating to system performance metrics.

The US ESRD healthcare ecosystem is currently operating in silos. Dialysis facilities, nephrologists, transplant centers, and OPOs are regulated separately and independently, yet function in an interdependent “ecosystem”. It’s been noted that a change in one system produces unintended consequences in another. Additionally, donor hospitals are currently not held accountable and have “no skin in the game” despite serving a crucial function in the organ supply chain.

Although there is general agreement that the current transplant center metrics are outdated, the question of what comes next and what new metrics should look like has been a more difficult question to answer. We propose that the goal/measure by which performance is assessed within the US system must provide **optimal benefit for people with kidney disease**. The HP2020 goals (HHS Office of Disease Prevention and Health Promotion) for access to transplant care were not met during the past decade. We want to use metric revision to address why and how to build a better kidney failure system.

President Trump proposed a powerful charge to improve Kidney Health in the country. The transplant community is ready and willing to participate in the effort. Our taskforce has agreed on several objectives to support this performance measure- that transplants are done safely, and the number of transplants is maximized. To reach this goal, we respectfully recommend:

- Bringing all stakeholders to the table in recognition of the potential for unexpected consequences when making changes to one part of the ESRD care continuum. We request that patient representatives (kidney groups) and kidney care providers (nephrologist/dialysis, transplant providers and OPOs that are charged with providing the kidneys) meet with representatives from government charged with overseeing the quality and performance of ESRD care (Office of the Secretary, CMS, HRSA and OPTN and CDC) to discuss methods to make our system more focused on benefiting persons with

¹ Chandraker, Anil, et al. “Time for Reform in Transplant Program—Specific Reporting: AST/ASTS Transplant Metrics Taskforce.” Wiley Online Library, John Wiley & Sons, Ltd, 23 May 2019, onlinelibrary.wiley.com/doi/10.1111/ajt.15394.

kidney failure. We are convinced that a better system can be developed, but it must be in concert with one another, and not in silos.

- Recognition that changes to OPO, dialysis facility and transplant center metrics need to be aligned. For example, increased organ recovery needs to be linked with increased utilization of organs by centers. This may mean changing how we consent transplant candidates and creating additional stratification of risk groups in order to use kidneys that are viewed to be at higher risk e.g. > 65-year-old DCD kidneys.
- Changes to quality metrics in dialysis facilities should also be well aligned with other health systems, including transplant centers. For example, the introduction of a new waitlisting metric for dialysis facilities, at a time when waitlisting is decreasing nationally due to the 2014 transplant allocation policy that disincentivizes waitlisting from a transplant program perspective, illustrates one area where the metrics are not well aligned.
- Considering what the appropriate denominator is for developing quality metrics –kidney candidates on the waitlist versus patients with ESRD?
- Considering who are the "right" donors
 - Developing a metric for deceased donors – What is a quality organ? Are the current outcome measures correct?
 - Developing a metric for living donation – How do we determine safe donation?
- Determining the appropriate measure of transplant success- how do we balance fairness versus utility?
- Determining how to address transplant centers that do not perform as well as they should? Best practices versus punitive measures that stifle transplantation.

We realize that the concept of “benefit” associated with system performance and changes in the patient denominator will require different discussion depending on the organ type to be considered. However, the imperative to address the kidney population has been prioritized by President Trump in his July 2019 Executive Order. We are actively engaged in these important discussions within our societies and look forward to working closely with you to find a resolution that will benefit our kidney patients, while meeting your regulatory needs. Please let us know how we might move forward with this important project.

Respectfully,



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