

May 22, 2020

The Honorable Thomas Engels  
Administrator  
Health Resources and Services Administration  
U.S. Department of Health and Human Services  
5600 Fishers Lane  
Rockville, MD 20857

RE: Modifying or Eliminating Arbitrary Kidney Transplant Center Outcomes Measures

Dear Administrator Engels:

On behalf of our physician and medical student members, the American Medical Association (AMA) is writing to **urge the U.S. Department of Health and Human Services (HHS) to create regulatory policies to advance kidney transplantation by modifying or eliminating arbitrary transplant center outcome measures** that currently discourage sound clinical judgment by physicians and surgeons to accept and transplant kidneys suitable for many patients.<sup>1</sup>

Approximately 37 million Americans have chronic kidney disease, and more than 726,000 have end-stage renal disease.<sup>2</sup> Despite this vast patient population, recent studies have shown that more than 17 percent of recovered kidneys, or 2,500, were discarded in 2013 regardless of evidence that many of these kidneys would have provided a survival benefit to certain wait-listed patients.<sup>3</sup> With over 100,000 people on the wait list to receive a kidney transplant, and an average wait time of over five years, these vital donations cannot keep going to waste.<sup>4</sup>

The U.S. is very likely to discard a kidney when the donor has hypertension, diabetes, a heart attack, or tested positive for Hepatitis C.<sup>5</sup> However, the presence of these conditions does not render the kidney unusable, and discretion of the physician combined with proper patient consent should be utilized to ensure that more of these kidneys are used. Moreover, research suggests that donor kidneys with similar characteristics to many kidneys that are currently discarded under transplant center outcome measures could have been successfully used for transplant and may provide a better survival rate and quality of life than remaining on the waiting list.<sup>6</sup>

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<sup>1</sup> <https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-16107.pdf>.

<sup>2</sup> <https://www.kidney.org/news/newsroom/factsheets/KidneyDiseaseBasics>.

<sup>3</sup> <https://www.ncbi.nlm.nih.gov/pubmed/26369343>.

<sup>4</sup> <http://www.lkdn.org/mission.html>.

<sup>5</sup> <https://www.usatoday.com/story/news/nation/2019/08/29/us-throws-away-3-500-donated-kidneys-per-year-study-says-heres-why/2139644001/>.

<sup>6</sup> [https://optn.transplant.hrsa.gov/media/1925/mpsc\\_txprogram\\_measures\\_20160815.pdf](https://optn.transplant.hrsa.gov/media/1925/mpsc_txprogram_measures_20160815.pdf).

The Honorable Thomas Engels

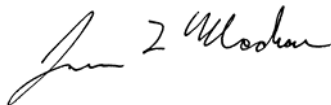
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To help address our nation's dire kidney shortage, HHS has stated that it wants to double the number of kidneys available for transplant by 2030, in part, by reforming the organ procurement and management system in the U.S.<sup>7</sup> However, the current post-transplant outcome review process creates disincentives for programs to transplant higher risk kidneys into patients due to concerns that the program will come under review if the transplants are not successful.<sup>8</sup> As such, HHS' reform must include modifying or eliminating arbitrary transplant center outcome measures, especially since studies have documented that excessive regulation and oversight have led transplant centers to risk-aversion donor criteria which excludes kidneys that could benefit many patients.<sup>9</sup> Thus, to increase the number of usable kidneys and decrease disincentives, **we urge HHS to improve risk-adjustment models that include better data that captures the acuity of candidate and donor risk, reconsider primary outcome measures to assess comprehensive transplant center performance, improve education to address rational or perceived disincentives, and utilize data more effectively to share best practices.**<sup>10</sup> Additionally, less punitive requirements for programs that employ new transplantation techniques to expand access should be implemented.<sup>11</sup>

The AMA urges HHS to review its regulations and oversight policies governing transplant centers in order to support the Executive Order on Advancing Americans' Kidney Health<sup>12</sup> and streamline the procurement process to encourage transplant centers to relax their donor criteria and accept more donor kidneys. Thank you in advance for your attention to this important matter.

Sincerely,



James L. Madara, MD

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<sup>7</sup> <https://www.hhs.gov/about/news/2019/07/10/hhs-launches-president-trump-advancing-american-kidney-health-initiative.html>.

<sup>8</sup> [https://optn.transplant.hrsa.gov/media/1925/mpsc\\_txprogram\\_measures\\_20160815.pdf](https://optn.transplant.hrsa.gov/media/1925/mpsc_txprogram_measures_20160815.pdf).

<sup>9</sup> <https://www.ncbi.nlm.nih.gov/pubmed/29217538>.

<sup>10</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5616160/>.

<sup>11</sup> <https://www.ncbi.nlm.nih.gov/pubmed/30520027>.

<sup>12</sup> <https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/>.