ASTS
American Society of Transplant Surgeons®

Saving and improving lives with transplantation.

February 3, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue S.W. Room 314G
Washington, DC 20201

Dear Administrator Verma:

As President of the American Society of Transplant Surgeons (ASTS), I thank you and your staff for the opportunity to meet with you on January 29, 2020. ASTS very much appreciates CMS' focus on the need to increase the availability of kidney transplantation. We look forward to working with you on the numerous initiatives launched by CMS to achieve this critical objective.

ASTS strongly supports the Administration's goal of doubling the number of clinically appropriate kidney transplants by 2030. We look forward to commenting on CMS' recent modifications of the OPO Conditions for Coverage (CfCs), which will play an important role in achieving this goal. Because the success of CMS efforts in this arena are likely to be significantly impacted by OPTN and SRTR Transplant Center outcome metrics that continue to disincentivize the transplantation of imperfect organs, we will be meeting with HRSA Administrator Engels this week to urge the removal or significant modification of these metrics. We will keep you apprised of our efforts to convince HRSA to harmonize the policies of its contractors with those advanced by CMS.

Importantly, we hope that you will consider expanding the scope of the Transplant Learning Collaborative to include living donation. This would significantly augment HRSA's efforts to expand living donor transplantation through potential expansion of the National Living Donor Assistance Center. Additionally, live donor kidneys are the most immediately available, offer a nearly limitless organ supply, and provide the best post-transplant outcomes. We are confident that with CMS and HRSA working together, the Administration's 2030 goal is achievable.

In order to succeed, however, it is critical to address the additional costs involved in the performance of kidney transplants that utilize higher risk organs or are performed for higher risk recipients. We had submitted a proposal for a voluntary CMMI demonstration project that would have addressed this issue by enabling a contracting entity (a collaborative including the area OPO, transplant center(s), donor hospital(s), dialysis facilities, and nephrologists) to share in the savings resulting from increasing the transplant rate over the area's historical baseline. This proposal (copy attached) was first submitted to Amy Bassano on November 7, 2017 and later to Tom Duvall at CMMI on other occasions.

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The Kidney Care Choices (KCC) Demonstration ultimately implemented by CMMI was not designed with the participation of the transplant community. Also, it does not address the higher cost and the need for additional payment for higher risk kidney transplants. However, we continue to believe that a focused demonstration program that provides an opportunity for increased Medicare payment for higher risk kidney transplants has the potential to increase transplantation rates, and that such an option could be designed to supplement the next solicitation for KCC participants (scheduled for later this year or early next year). We would be pleased to work with CMMI on this project.

Again, we appreciate the opportunity to meet with you and your staff. We very much look forward to future collaboration to achieve the goals of the Kidney Health Initiative.

Sincerely,

Lloyd E. Ratner, MD, MPH, FACS, FICS(Hon)
President
American Society of Transplant Surgeons

Cc:
Marion Everett Couch, MD, PhD, MBA, Senior Medical Advisor, Office of the Administrator, CMS
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Care Coordination to Increase Transplantation Demonstration Project

This outlines a proposed demonstration project structured to increase transplantation for Medicare patients with kidney disease by providing financial incentives and regulatory relief to transplant centers, dialysis facilities, Organ Procurement Organizations (OPOs,) community hospitals, nephrologists and others to increase transplantation rates in the area covered by the demonstration project.

Background

It is undisputed that kidney transplantation is most often the best treatment option for Medicare patients with ESRD and potentially for Medicare patients with kidney disease short of ESRD (hereafter, "Demonstration-eligible patients"). It is also undisputed that kidney transplantation is the most cost-effective treatment for such patients. However, under today's Medicare program, dialysis is the usual treatment for these patients and transplantation is the exception. Rather than the status quo, transplantation should be the first line treatment, with dialysis available for those patients for whom transplantation is contraindicated and those for whom a suitable organ is unavailable.

Misaligned Incentives to Transplant

The Medicare program includes a number of financial and regulatory disincentives for providers to maximize the use of transplantation as the treatment of first choice for Demonstration-eligible patients. On the financial side, dialysis facilities and associated nephrologists have a strong financial incentive to maintain patients on dialysis as long as possible. OPOs, which are paid by Medicare on a cost basis, have little financial incentive to increase the supply of viable organs. Non-transplant hospitals—a potential source of additional organ donors—have no financial incentive to ensure that OPOs are fully and effectively informed in a timely manner of potential organ donors.

Regulatory Rules, Existing Demonstration, & Legislative Challenges

Current Medicare regulations do not encourage, and in some ways actively although inadvertently discourage, increased transplantation. OPO conditions of participation dissuade OPOs from retrieving kidneys from kidney-only donors. Transplant Center conditions of participation impose outcomes requirements that dissuade centers from accepting "marginal" organs for transplantation. Dialysis facilities are required to counsel patients on the availability and benefits of transplantation but often fail to do so (or fail to do so effectively). Neither nephrologists' quality measures nor dialysis facility quality measures address referrals for transplantation evaluation. And reimbursement to potential living donors for the costs associated with donation is limited by concerns over NOTA prohibitions.

The ESRD CEC demonstration program currently underway as well as legislation introduced in the last Congress (the "PATIENT Act") would encourage dialysis facilities and others to maintain patients on dialysis rather than referring appropriate patients for transplant evaluation: shared savings would cease in the case of the CEC demonstration program, and capitated payments would decrease substantially in the case of the PATIENT Act.

THE DEMONSTRATION CONCEPT

Goals. Increase transplantation for Medicare patients with kidney disease by providing financial incentives and regulatory relief to transplant centers, dialysis facilities, OPOs, community hospitals, nephrologists and others to increase transplantation rates in the area covered by the demonstration project.

Changing the Paradigm of Dialysis & Transplantation. The patient cost of transplantation, over a short period of time, is far less than dialysis; patient life expectancy for transplantation is far longer than dialysis; savings to the Medicare program would increase if transplant were advanced more methodically.

- The United States Renal Data System (USRDS) 2015 Report[1] notes that total Medicare expenditures per person/per year for hemodialysis patients is $84,550; for those on peritoneal dialysis, $69,919; and for renal transplantation, $29,920[1] (approximately $34,795/year including estimated Part D expenses).

- The average expected duration of the benefit of therapy after renal transplantation is twice that of hemodialysis[2]: Life expectancy for hemodialysis is 5.7 years with nearly universal mortality and for renal transplantation 12 years ("graft survival") with 25% mortality.

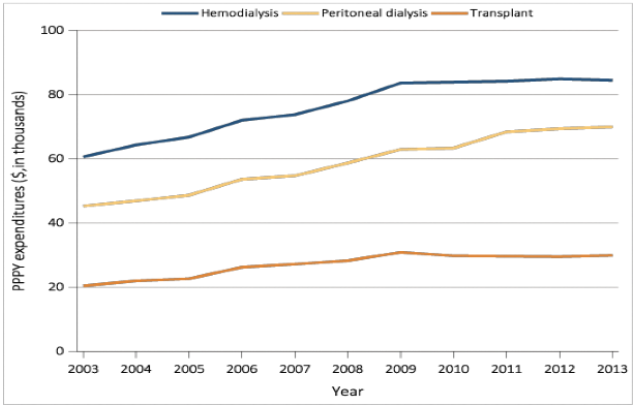
- Thus, total Medicare savings for each patient who is transplanted rather than being maintained on hemodialysis is estimated at $283,603 over the average 5.7 lifespan on hemodialysis, based on USRDS data. And, based on the cost trends for dialysis and transplantation, it appears that the savings are likely to grow over time.

[1] USRDS 2015 Annual Report, http://www.usrds.org/adr.aspx, accessed March 2016.

[2] *Id. Data Source: USRDS ESRD Database; Reference Table K.7,K.8,K.9. Period prevalent ESRD patients; patients with Medicare as secondary payer are excluded. Abbreviations: ESRD, end-stage renal disease.*

- Additional published data also suggests that considerable cost savings would result from increasing transplantation for clinically appropriate patients.[3]

Total expenditures per Medicare ESRD person per year, by modality



Changing Financial Incentives, Removing Disincentives. Instead of continuing to allow the misalignment of incentives and perpetuating disincentives to transplant, all providers involved in the care of Demonstration-eligible patients should receive a financial incentive to increase transplantation of clinically appropriate patients, using a shared savings (and potentially shared losses) incentive system similar to that used under the ACO program and various Centers for Medicare and Medicaid Innovation Center (CMMI) demonstration programs.

DEMONSTRATION PARAMETERS

- CMS would determine a target number[4] of transplants for the demonstration area by determining the average number of transplants historically performed in the demonstration area, updating that number as appropriate to cover the time period of the demonstration, and making other appropriate adjustments.

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[3] Additional published analyses support the considerable cost savings that are achievable through transplantation. See, e.g. Matas, AJ, Schnitzler, M. Payment for Living Donor (Vendor) Kidneys: A Cost-Effectiveness Analysis. American Journal of Transplantation 2004; 4: 216–221 http://www.ncbi.nlm.nih.gov/pubmed/14974942. ; Whiting, James F.; Woodward, Robert S.; Zavala, Edward Y.; Cohen, David; Martin, Jill E. ; Singer, Gary G.; Lowell, Jeffrey A.; First, M. Roy; Brennan, Daniel C.; Schnitzler, Mark A. Economic Cost of Expanded Criteria Donors in Cadaveric Renal Transplantation: Analysis of Medicare Payments. Transplantation. 9/15/2000 - Volume 70 - Issue 5. http://journals.lww.com/transplantjournal/Abstract/2000/09150/ECONOMIC_COST_OF_EXPANDED_CRITERIA_DONORS_IN.7.aspx.

[4] It may make it more attractive to CMS if the target is established such that Medicare it exceeds annual renal transplants by some number, so that the Medicare program does not have to pay the demonstration participants for savings resulting from the first "x" number of transplants that exceed historic rates.

- Participants in the demonstration program (consisting of transplant center(s), dialysis facilities, the OPO, physicians, and community hospitals) would be paid their fee-for-service rates under whatever Medicare payment system ordinarily applies.
- For each additional Medicare ESRD patient transplanted over the target, savings equal to some percentage of the average difference between the cost of transplantation and the cost of dialysis would be paid into a separate segregated account established by the demonstration participants and managed by a third-party trustee.
- Payments would continue for the average 5.7-year lifespan of patients undergoing dialysis, unless the transplanted patient dies, requires dialysis, or requires re-transplantation. (Separate shared savings calculations could be made for Medicare patients who have renal disease and who are clinically appropriate for pre-emptive transplantation but who are not yet on dialysis.)
- Funds paid into the separate segregated fund are distributed by the trustee among demonstration participants based on an agreement among the participating providers and approved by CMS prior to inception of the demonstration project.
- Phase II of the program might include an option under which the program participants could share the losses in the event that transplants do not meet the target.
- Demonstration Program would last for five years (with potential savings distributable for 10.7 years from inception of the program).

Regulatory Relief. In addition to the financial incentives described above, demonstration participants could be entitled to waiver of certain otherwise applicable Medicare rules. For example, Congress could require CMS to:

- Waive or liberalize the outcomes requirements applicable to participating transplant centers, so long as outcomes equal or exceed outcomes of dialysis or some other negotiated benchmark.
- Waive OPO conditions of coverage to encourage OPOs to pursue single organ donors.
- Allow National Living Donor Assistance Center to reimburse lost wages for living donors who meet established financial criteria.
- Waive OPO cost reporting principles to enable program participants to establish an OAC for organs for paired kidney donation.
- Enable transplant centers to count as an “in house donor” any donor who was declared deceased and consent was authorized in its facility. These donors can then be cared for in more cost-effective organ recovery centers that are now being established by OPOs, without adversely impacting transplant center revenue while simultaneously decreasing the cost of transplantation and potentially increasing organ recovery.
- Enable program participants to pay for immunosuppressive coverage beyond 36 months.
- Provide that participation in the demonstration program constitutes a Clinical Practice Improvement Activity and could include a measure relating to nephrologist referrals for transplantation evaluation as a quality measure under MIPS. (It is unclear that the demonstration project would qualify as an “Advanced Alternative Payment Model” without additional risk-bearing features.)

Conclusion

The proposed demonstration project has the potential to achieve considerable savings for the Medicare program while substantially improving the care for ESRD patients and other Medicare patients with renal conditions for which transplantation is clinically appropriate. By aligning incentives and encouraging care coordination, the demonstration program has the potential to significantly increase the availability of transplantation for Medicare patients for whom transplantation is the best and most cost-effective treatment option.

Finally, we note that there are a number of other regulatory changes that could be made that would facilitate the success of the proposed demonstration project. Specifically, while CMS has proposed to eliminate its outcomes requirements as a condition of Medicare re-approval —a proposal that ASTS strongly supports—outcomes requirements continue to be imposed by two organizations under the jurisdiction of HRSA.

In particular, the OPTN through the UNOS Membership and Professional Standards Committee (MPSC) continues to impose strict outcomes requirements on transplant centers. To compound the issue, the SRTR has instituted a new five-star rating system for transplant centers that strongly encourages transplant centers to engage in risk averse behavior in patient selection and organ acceptance and that may discourage transplantation and result in transplant-eligible ESRD patients remaining on dialysis. These requirements have the potential to interfere with the success of the demonstration project, and we especially urge CMS to discuss with HRSA the urgent need to reinstitute the prior three tier star rating system, to focus on patient survival rather than graft failure post-transplant, and to provide additional data to the centers as confidential, protected quality data for internal use and review. A bullet point list of concerns with proposal is summarized below:

1. The five-tier system to assess transplant center performance: HRSA has directed the SRTR to create a new 5-tier grading system. This system replaced the existing 3-tier system in which >90% of programs were graded as either as expected or above. The new system forces 40% of programs into the lowest two tiers of programs despite the lack of evidence that outcomes are actually worse.

    - The 5-tier system will force centers to become even more risk averse. If payers and patients see anything less than a 4 or a 5 as less than acceptable, centers will stop taking risks.
    - The 5-tier ratings are very fluid. The movement between centers is significant and waiting times are long. Therefore, listing a 5-star program now may lead to transplant at a 3-tier after waiting time.
    - There is little to no correlation between the tier of the program at the time of listing and survival. Thus, it does not inform patient choice but does lead to fear among patients, overly conservative transplant practice, and distrust of the system.
    - It does a poor job informing patients about transplant rates despite their interest in understanding this aspect of care. The current presentation is confusing as it does not report rates for comparable centers and appears to show that centers in regions with

longer waiting lists are poor performers. This will lead to greater reluctance to place patients on the waiting list.

Proposal: Instruct HRSA to request that the SRTR return to the prior 3-tier system of ratings and consider removing public reporting of graft failure. Focus on patient survival post-transplant. Provide additional data to the centers as confidential, protected quality data for internal use and review.

References:

1) Expanding clarity or confusion? Volatility of the 5- tier ratings assessing quality of transplant centers in the United States. Schold et al. 2017
2) Patients prioritize waitlist over posttransplant outcomes when evaluating kidney transplant centers. Husain et al. AJT 2018
3) Comparing Scientific Registry of Transplant Recipients posttransplant program-specific outcome ratings at listing with subsequent recipient outcomes after transplant. Wey et. al 2018
4) Utilizing High-Risk Kidneys—Risks, Benefits, and Unintended Consequences? D. A. Axelrod and J. J. Friedewald. AJT 2016
5) Measuring What Matters. Axelrod and Schold. AJT 2016