November 7, 2017

Ms. Amy Bassano
Acting Director
Center for Medicare and Medicaid Innovation
U.S. Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Bassano:

On behalf of the American Society of Transplant Surgeons, we are pleased to have the opportunity to respond to the CMMI Request for Information regarding its proposed New Direction. ASTS is a medical specialty society representing approximately 1,800 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through leadership, advocacy, education, and training.

We wish to comment on CMMI focus on new specialty care models, as described in the RFI. ASTS strongly supports CMMI's proposal to initiate new demonstration models related to specialty care. Specifically, we urge you to consider implementing a new demonstration project along the lines described below to increase the availability of transplantation as a treatment option for Medicare beneficiaries with End Stage Renal Disease (ESRD). Implementation of such a demonstration has the potential to improve positive health outcomes for these patients while substantially reducing costs.

The Role of Transplantation in the Treatment of ESRD

It is critically important that Chronic Kidney Disease (CKD) and ESRD patients' access to transplantation as a treatment option be increased. The average kidney transplant recipient lives more than twice as long as he/she would if remaining on dialysis (USRDS data) and enjoys markedly improved quality of life and longevity: Life expectancy after starting dialysis is 5.7 years, and after kidney transplantation, life expectancy is 15.8 years. Preemptive transplantation performed prior to the increased expenditures incurred at the start of dialysis is also associated with almost doubling of 10-year patient survival compared to later transplantation and is the preferred treatment for all eligible patients. Moreover, transplantation is also by far the most cost-effective treatment option for patients with Advanced CKD and ESRD. Kidney transplantation is associated with a cost savings of as much as $200,000 per transplant over the first 5 years after transplantation. (Examination of

Medicare spending reveals the breakeven point for transplantation vs. dialysis is 2.3 years for patients who undergo living donor transplantation and 3.6 years for recipients of deceased donor transplantation.) To the extent that, in the context of the current dialysis-based model, ESRD facilities fail to educate their patients regarding transplantation options or to refer their patients for transplant evaluation as clinically appropriate, this failure has the potential to increase ESRD costs of care. In short, it is undisputed that kidney transplantation is often not only the best treatment option for Medicare patients with ESRD and potentially for those Medicare patients with kidney disease short of ESRD, who may be eligible for pre-emptive transplants (collectively, "Demonstration-eligible patients"), but also 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. The Healthy People (HP) 2020 initiative includes a number of goals related to transplantation that have not been met. 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

Because of the focus on the dialysis patient and the dialysis provider, 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. Furthermore, the transplant ecosystem that includes the transplant hospitals and the entities that make organs available, such as the donor hospitals and the Organ Procurement Organizations (OPOs), have been ancillary and not integral to ESRD care. Because of the dialysis-centric model, 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.

Current Medicare regulations do not encourage and in some ways actively (although inadvertently) discourage increased transplantation on the part of the transplant centers due to transplant center conditions of participation outcomes requirements that dissuade centers from using less than ideal organs or transplanting patients whose health conditions increase the risk of affecting the center outcomes statistics. 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 prohibitions in the National Organ Transplantation Act (NOTA) related to financial inducements.

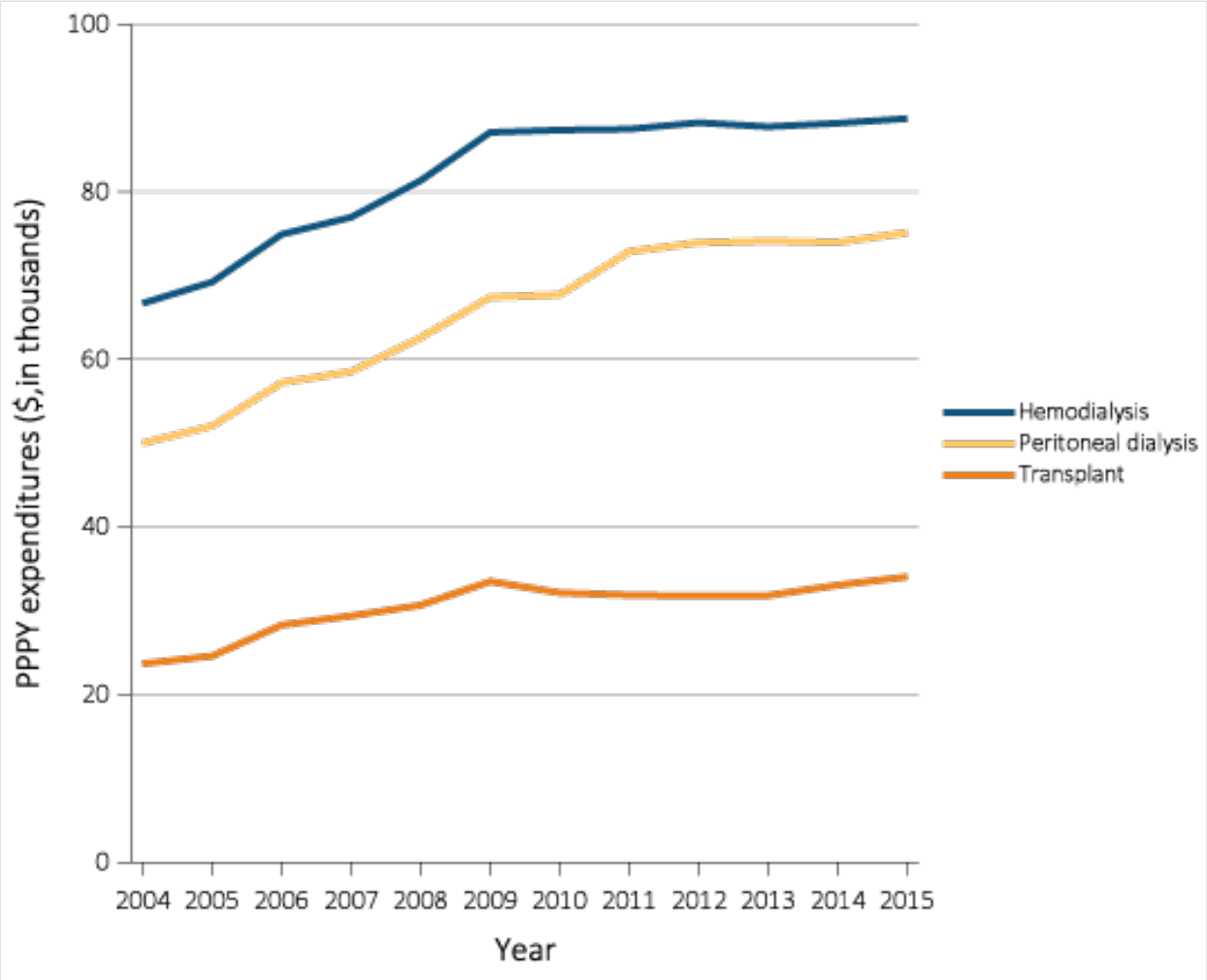
The Demonstration Concept

Goals

The goal of the proposed demonstration project is to increase transplantation for Medicare patients with kidney disease by providing financial incentives and regulatory relief to the transplant ecosystem—including transplant centers, dialysis facilities, OPOs, community hospitals, nephrologists, and others—to increase transplantation rates in the area covered by the demonstration project (and possibly to increase the number of transplantable organs from the area overall, including organs "exported" to other geographic areas).

Changing the Paradigm of Dialysis & Transplantation
The per-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) 2017 Report[1] notes that total Medicare expenditures per person/per year for hemodialysis patients is $88,750; for those on peritoneal dialysis, $75,140; and for renal transplantation, $34,084.[1]



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. [2]

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[1] USRDS 2017Annual Report, https://www.usrds.org/adr.aspx, accessed November 2017.

[2] 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

Changing Financial Incentives, Removing Disincentives
Instead of continuing to allow the misalignment of incentives and perpetuating disincentives to transplant, the proposed Demonstration Program seeks to capture the savings attributable to increased transplantation and to share a portion of those savings with the providers participating in the demonstration program. Savings could be shared based on a shared saving incentive system similar to that used under the Medicare Shared Savings Program (MSSP) and various other CMMI demonstration programs.

While many details of the proposed model would need to be further developed and while it may be necessary to change some features of the model as discussions progress, our preliminary outline of the steps that would be involved is set forth below:

- CMS, using publicly available data sources and in conjunction with the transplant community, would determine a target number 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.
- Participants in the demonstration program (consisting of a consortium 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.
- In conjunction with analysts from the USRDS (who have established costing techniques in this area), CMS would determine the average savings of transplantation over other renal replacement therapies (i.e., various forms of dialysis). The average length of time over which such savings accrue also would be determined, and the demonstration duration would be established such that all savings attributable to transplantation are fully taken into account.
- 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 preparation for dialysis (for preemptive patients) and dialysis for ESRD patients would be paid into a separate segregated account established by the demonstration participants and managed by a third party trustee.
- Separate shared savings calculations could be made for Medicare patients who have renal disease and who are clinically appropriate for preemptive transplantation but who are not yet on dialysis. In addition, shared savings also could be paid if the number of organs retrieved and "exported" for transplantation in a different area were increased over baseline calculations.
- 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.

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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.

- 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.

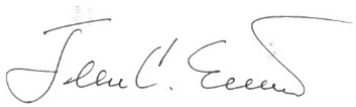
Regulatory Relief
In addition to the financial incentives described above, demonstration participants could be entitled to waiver of certain otherwise applicable Medicare rules. For example, Congress could require CMS to:

- Modify the outcomes requirements applicable to participating transplant centers to minimize existing organ discard rates and to incentivize preemptive and ESRD patient access to transplantation.
- Waive otherwise applicable OPO cost-finding principles to the extent necessary to provide a financial incentive for OPOs to increase the number of organs recovered.
- Allow the National Living Donor Assistance Center (NLDAC) to reimburse living donors who meet expanded financial criteria for lost wages.
- Waive OPO cost reporting principles to enable program participants to establish an OAC for organs for paired kidney donation.
- Waive otherwise applicable restrictions on payments to beneficiaries to allow the consortium to provide transplantation and patient incentives to maintain eligibility for transplantation while on the wait list.
- Provide that participation in the demonstration program constitutes a Clinical Practice Improvement Activity and 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 possibly other Medicare patients with renal conditions for which transplantation is clinically appropriate.

Others in the transplant community have expressed interest in a demonstration model along the lines outlined above, and we look forward to further discussions with you regarding the possibility of instituting such an effort as part of CMMI's new focus on specialty models under its "New Directions" initiative. If you have any questions, please feel free to contact ASTS Executive Director Kim Gifford at kim.gifford@asts.org or 703-414-7870.

Sincerely,



Jean Emond
President, ASTS