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American Society of Transplant Surgeons®

October 17, 2023

Dear Tom,

This letter is to follow up on our recent discussion regarding a potential CMMI demonstration project focused on increasing living and deceased donor transplants (“Demonstration Project”). ASTS is committed to partnering on this Demonstration Project with you and are deeply appreciative of your continued interest and engagement.

Based on our most recent discussion, it is our understanding that CMMI is currently thinking through several aspects of the potential Demonstration Project, including:

- (a) if, and under what conditions, start-up funds should be made available to demonstration participants in advance of patient enrollment;
- (b) previously proposed elements we advise discarding from the model;
- (c) the amount of the incentive; and
- (d) how targets should be determined.

Detailed below are our thoughts regarding each of these components of what we hope is a shared vision for a Demonstration Project that will decrease disparities, increase equity in access, and increase overall living and deceased donor kidney transplant volumes.

A). Advanced Payment for Project Participants

We believe that it would be useful for CMMI to make available information on advance payment for transplant programs for Demonstration Project participants. While we do not believe that most larger programs would require or elect such advance payments, smaller transplant programs may have such needs. Smaller programs often have limited funds available to establish or enhance their living donor transplant programs or to make the expenditures necessary to increase access to deceased donor transplantation. Having an advanced payment option available to participants would likely increase the real or perceived accessibility of the Demonstration Project for smaller transplant programs.

Because Medicare is the primary payer for kidney transplantation, a significant portion of the costs likely to be incurred by small programs that seek to participate in the Demonstration Project would be eligible for reimbursement via organ acquisition cost (OAC) Medicare reimbursement. For example, the salary and benefit costs of an additional transplant coordinator or other dedicated transplant staff necessary to increase the number of transplants that a smaller program performs ultimately should be eligible for Medicare payment as OAC to the extent that kidney transplant recipients are Medicare patients. To the extent that advance payments are made to small transplant program participants for expenses that would otherwise constitute OAC, no repayment should be required. Given that the primary purpose of the CMMI advance payment is to make these funds available earlier, to the extent that advance payments exceed otherwise reimbursable OAC, consideration could be given to writing off some proportion of the difference from otherwise payable OAC if the transplant program fails

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to meet its targets within the Demonstration Project.

Additionally, advance payments made with the overt intent to improve equity in and decrease disparities in access to transplantation should not be subject to repayment for failure to meet specified targets. For example, a Demonstration Project participant may wish to subsidize the transportation, childcare, lost wages, or other expenses incurred by potential transplant recipients who are financially disadvantaged, are from a historically underserved population, or may wish to subsidize such expenses for living donor candidates who cannot obtain reimbursement from other sources. We do not believe that expenditures of this kind should be subject to repayment.

B). Elements we propose to discard from the proposed Demonstration Project model.

All prior iterations of the Demonstration Project we have discussed emphasized the importance of combining financial incentives based on the shared cost savings attained from additional transplant volume coupled with regulatory relief in the form of waivers of some OPTN and SRTR star ratings performance metrics. We remain concerned that existing performance metrics provide a disincentive to transplantation of higher risk candidates and the utilization of higher risk kidneys. We recognize that CMMI does not have the authority to mandate waivers of OPTN or SRTR outcomes requirements, and it is not clear that any initiative pursued by the transplant community along these lines would be successful. This pragmatic assessment means that the primary incentive within the model will be the financial incentives from a portion of the shared cost savings, and those incentives, discussed below, therefore assume even greater importance.

C). The Financial Incentive

Another critical subject of our recent conversations was determining the amount of the financial incentive provided to transplant program participating in the Demonstration Project for achieving increases in transplant volume relative to historic baselines. We believe that the amount of the financial incentive should be based on a percentage of the cost savings of transplantation over dialysis. The most recent available USRDS Annual Report (for 2022) indicates that the per patient per year Medicare expenditures for beneficiaries with ESRD in 2020 were as follows (in inflation adjusted dollars):

Hemodialysis:	\$95,932 PPPY
Peritoneal Dialysis:	\$81,525 PPPY
Transplantation:	\$39,264 PPPY

We propose that CMMI determine the weighted average PPPY cost of ESRD patients on dialysis and base incentive payments on a percentage of the difference between the weighted average of PPPY costs of patients on dialysis vs. those who are transplanted. For example, assuming approximately 85% of dialysis patients are on hemodialysis and 15% on peritoneal dialysis, the PPPY cost of ESRD patients on dialysis based on the USRDS data set forth above would be \$93,771, and the estimated cost savings PPPY of transplantation over dialysis would be approximately \$54,507 PPPY. Using these figures, the five-year savings for transplantation versus dialysis would be approximately \$272,533. If CMMI sets the incentive payment shared with the Demonstration Project participant at 10% of the estimated five-year savings of transplantation over dialysis, the financial incentive would be approximately \$27,533 for each additional transplant performed over the baseline. Negative adjustments could be made if the program's expected 90-day or 1-year conditional patient survival were significantly lower than expected, and positive adjustments could be made to specifically incentivize improvements in equity or increases in pre-emptive transplantation.

D). Determining Targets

As indicated in our prior correspondence, we believe that demonstration participants should be divided into tiers depending on the size of the program and that those targets should be different for low, medium, and large volume transplant centers. To the extent practicable, targets should be negotiated individually with each demonstration participant, to account for transplant centers' widely varying characteristics including, for example, the size and effectiveness of their current living donor programs and their current organ acceptance practices.

CMMI may wish to consider establishing minimum increases in the number or percentage of transplants performed for each tier, and then engaging directly with select applicants to establish additional targets.

We hope that these thoughts are helpful to CMMI in thinking through the operational details of the proposed Demonstration Project. We continue to be committed to the concept of a Demonstration Project and passionate about the strategic and ethical importance of the underlying goals of decreasing disparities, increasing equity in access, and increasing overall living and deceased donor kidney transplant volumes. We know that you and your team share that passion to improve the transplant system and are appreciative of the time and effort CMMI has expended on this project to date. Please reach out at any time to discuss the above items or any other aspect of the Demonstration Project model.

Sincerely,

A handwritten signature in black ink that reads "Elizabeth A. Pomfret". The signature is written in a cursive, flowing style.

Elizabeth A. Pomfret, MD, PhD, FACS
President