March 3, 2020

Demetrios Kouzoukas, JD
Principal Deputy Administrator and Director
Office of the Administrator
Center for Medicare

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2021 Call Letter Part II **(Advance Notice)**

and

RIN 0938-AT97, file code CMS-4190-P: Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly **(Proposed Rule)**

Dear Mr. Kouzoukas:

On behalf of the American Society of Transplant Surgeons (ASTS), we are pleased to have an opportunity to comment on the Medicare Advantage (MA) 2021 Advance Notice of Methodological Changes (Advance Notice) and the Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program (the Proposed Rule). ASTS is a medical specialty society representing over 1,800 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

Our comments focus on issues of potential concern to Medicare patients with ESRD who may be enrolled in a MA plan, either under current law or under the eligibility expansion enacted in the 21st Century Cures Act. The 21st Century Cures Act for the first time will enable ESRD-eligible Medicare beneficiaries to enroll in MA plans. While the Advance Notice and the Proposed Rule each address somewhat different aspects of this eligibility expansion (with substantial overlap), we believe that the comments below are relevant to both issuances.

I. Access to Transplantation for Medicare Beneficiaries Enrolled (and to be Enrolled) in MA Plans.

As noted in the regulatory impact statement accompanying the Proposed Rule, CMS anticipates that, when ESRD-eligible Medicare beneficiaries become eligible to enroll in MA plans in 2021, the number of ESRD patients enrolled in MA plans will increase by 83,000 due to the Cures Act provision. It is further anticipated that about half of these beneficiaries will enroll in 2021, thereby increasing the number of ESRD patients in MA plans by over 20% in a single year.

The same regulatory impact statement notes that the transplant incidence rate for ESRD patients in Medicare FFS has historically often been more than three times the MA incidence rate.

Based on these observations, we are concerned about potential barriers to access to transplantation both for ESRD patients already enrolled in MA plans and those who will become newly eligible under the 21st Century Cures eligibility expansion. In the Kidney Health Initiative initiated last year, the Administration announced its goal of doubling the number of ESRD patients transplanted by 2030. In light of the growth of the anticipated expansion of MA plan options to ESRD-eligible Medicare beneficiaries, we believe that it is critical that MA plans improve their historical underperformance with respect to transplantation of enrollees with ESRD. We urge CMS to consider the following policy proposals to achieve this objective:

Recommendation: Expand the availability of transplant bonuses to MA plans. The Center for Medicare and Medicaid Innovation (CMMI) last year announced a new voluntary demonstration program under which organizations willing to fully accept financial risk for Medicare beneficiaries with ESRD (e.g., accepted capitated payment comparable to that paid to MA plans) would be eligible for "transplant bonuses" of $15,000 (payable over three years) for each transplant performed for an attributed beneficiary. While the application deadline has passed for the first round of applications, CMMI has indicated that it intends to open a second round later in 2020 or 2021. We recommend that CMS consider making MA plans eligible for the transplant bonus so long as conditions similar to those imposed on other applicants are met (i.e., involvement of a transplant provider in program governance and sharing of a designated percentage of the transplant bonus with a transplant provider).

Recommendation: Impose Network Adequacy Requirements for Transplant Centers. The Advance Notice and Proposed Rule describe the methodology used by CMS to assess MA plan network adequacy. This methodology does not specifically include a focus on the inclusion of an adequate number of transplant providers (i.e., transplant physicians, transplant surgeons, and transplant centers) in the network. We request that, in light of the importance of access to transplantation for enrollees with ESRD, network adequacy standards should be developed for transplant providers and that MA plan bids be assessed specifically to ensure that a sufficient number and distribution of transplant professionals and centers are accessible.

Recommendation: Ensure Adequate Payment for Transplantation Procedures Performed for MA Enrollees. It is our understanding that, under the payment methodology that will be in effect in 2021, to cover transplant costs other than organ acquisition, the ESRD Rate is adjusted using a "transplant factor" for a three month period (the month of transplantation and two subsequent months) for any beneficiary who is transplanted. The applicable Age/Disabled Rate is used thereafter with certain special risk adjustments. Under the provisions of the 21st Century Cures Act, organ acquisition costs are to be directly paid by the Medicare Program under the same methodology used for FFS beneficiaries.

We understand that the "transplant factor" is determined in a manner calculated to reflect the state-wide average cost of transplantation. Significantly, however, there may be significant variation in the non-organ acquisition costs of transplantation within a state, and transplant factors based on a state-wide average transplant cost rate may significantly underpay some transplant centers. For this reason, we recommend that CMS consider modifying the payment formula to determine the transplant factor based at least in part on the historical costs of the transplant center involved.

Recommendation: Monitor Impact of Payment Differential Between Post Transplant Enrollees and Those on Dialysis. As set forth in our prior comments, we are concerned that MA capitation payment for

post-transplant enrollees is approximately one-tenth the amount paid for those enrollees on dialysis, and that this differential has the potential to dissuade MA plans from aggressively making transplant options available to those enrollees on dialysis and educating enrollees about the clinical advantages of transplantation. On the other hand, we are aware that some data suggests that dialysis facilities can negotiate a significant premium for their services as the result of market concentration. In areas where this is true, MA plans may encourage transplantation, despite the substantial differential in the payments made by CMS for those on dialysis and those who have received a transplant. Because at this stage it is unclear how these various incentives and counter-incentives will play out, we request that CMS specifically require MA plans to report their transplant rates and monitor access carefully as ESRD-eligible beneficiaries begin to enroll in MA plans.

II. Technical Issues:

We also request that CMS address a number of technical issues that have the potential to significantly impact Medicare beneficiaries' access to transplantation both under MA and under original Medicare.

Recommendation: Provide Direct Payment to Providers for Organ Acquisition Costs. The Proposed Rule and Advance Notice both acknowledge that the 21st Century Cures Act mandates payment for organ acquisition costs under the same methodology used for the payment of these costs under original Medicare. However, neither document specifically and clearly states that these services are to be billed directly to Medicare Administrative Contractors (MACs) and will be paid directly to the providers involved, rather than being paid to MA plans for pass-through to providers. We urge CMS to clarify this in the final rule and to ensure that MA plans understand that, as defined under applicable Medicare FFS rules and Manual instructions, organ acquisition costs payable directly by original Medicare include not only costs directly related to the acquisition of an organ, but also essentially all pre-operative items and services provided to potential recipients, including but not limited to transplant evaluation costs for potential recipients and living donor costs.

Recommendation: **Modify Medicare Manual Provisions to Ensure Accurate Medicare Payment for Organ Acquisition Costs**. Under the current MA payment methodology, organ acquisition costs are not reimbursed separately based on the methodology applicable under original Medicare. Rather, organ acquisition costs are included in the transplant adjustment factor paid by the Medicare program to MA plans. Accordingly, organ acquisition costs are included in rate negotiations between MA plans and transplant providers, just as they are included in the rate negotiations between other private payers and transplant providers and are not included in determining Medicare's share of total organ acquisition costs payable by Medicare (the "Medicare percentage").

However, under 21st Century Cures, the organ acquisition costs attributable to MA transplant recipients and potential recipients are to be paid just like the organ acquisition costs for original Medicare transplant recipients. For this reason, beginning in 2021, MA enrollee organ acquisition costs should be included in the "Medicare percentage" used to determine Medicare's share of organ acquisition costs. It is critical that applicable provisions of the Medicare Manuals be modified to ensure that MA enrollees are "counted" as Medicare patients for purposes of determining the Medicare percentage, to avoid significant potential underpayment of the organ acquisition costs attributable to Medicare patients.

Recommendation: **Ensure that MA Transplant Recipients are Included in Records Used to Determine Post-Transplant Immunosuppressant Coverage Under Part B**. As noted in the Regulatory Impact Statement accompanying the Proposed Rule, it is anticipated that the eligibility expansion enacted by 21st Century Cures will substantially increase the number of Medicare beneficiaries with ESRD covered under MA. At least some ESRD-eligible MA transplant recipients may choose original Medicare after their transplants, and they are entitled to three years of post-transplant Part A and Part B eligibility.

We understand from prior Advance Notices that there have been a number of operational issues that have complicated post-transplant access to immunosuppressants: Medicare Part B coverage is available only for those whose transplants were covered by Medicare and—even for original Medicare transplant recipients—accurate information on whether or not the original transplant was covered by Medicare is not always accessible to pharmacies dispensing immunosuppressants. We encourage CMS to examine its operational systems to ensure that MA transplant recipients are accurately included in the databases used to determine eligibility for post-transplant immunosuppressant coverage under Medicare Part B.

We appreciate the opportunity to comment on the Advance Notice and the Proposed Rule. If you have any questions about these comments, or need any further information, please do not hesitate to contact ASTS Advocacy Manager Jennifer Nelson-Dowdy (Jennifer.Nelson-Dowdy@asts.org).

Sincerely yours,

Lloyd E. Ratner, MD, MPH, FACS
President