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American Society of Transplant Surgeons®

March 1, 2019

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) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter (CMS-2018-0154)

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) 2020 Advance Notice of Methodological Changes and Draft Call Letter (Draft Call Letter). 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 patient care, research, education, and advocacy. Our comments focus on issues related to the proposed ESRD Rate, Risk Adjustment and other matters 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.

As indicated in our comments on last year's call letter (attached), we would anticipate that an increased number of our patients and potential patients may be enrolled in a MA plan beginning in 2021. In last year's comments, we raised concerns that the then proposed 2019 unadjusted rate paid to a MA plan for an enrolled ESRD beneficiary on dialysis was about 10 times the unadjusted rate paid for a post-transplant patient. In its final call letter, CMS acknowledged this comment but indicated confidence that the rate adjustment methodology would address our concerns.

For 2020, CMS is proposing important changes to the Part C risk adjustment model based on section 1853(a)(1)(I) of the Social Security Act (the Act). This proposal reflects the requirement in the 21st Century Cures Act (Pub. L. 114-255) to take into account the number of conditions an individual beneficiary may have, making an adjustment as the number increases. The resulting risk adjustment methodology, as it relates to Medicare beneficiaries with ESRD, is extremely complex and technical, and, for this reason, it is unclear to us whether and to what extent the new risk adjustment methodology will exacerbate or reduce the differential between the capitation rates paid for ESRD patients on dialysis and those who have received a transplant. In order

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American Transplant Congress

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to provide additional transparency with respect to this issue, we request that the final Call Letter provide illustrations of the capitation rates that will be payable to MA Plans for enrollees with similar clinical profiles, depending on whether or not the beneficiary is on dialysis or has received a transplant.

We do note, however, that there are some indications that the new risk adjustment methodologies do not accurately capture the costs associated with dialysis or post-transplant recipients. For example, the Call Letter indicates that the risk adjustment model now proposed by CMS under-predicts the costs of newly enrolled post-transplant patients and over-predicts the costs of newly enrolled dialysis patients (by 15%). See Advance Notice of Methodological Changes at pp. 31-32. While CMS is making adjustments to address these issues, these findings reinforce our concerns that risk adjustment methodologies do not compensate for the large discrepancy in the standardized rates payable for ESRD enrollees on dialysis and those in post-transplant status.

While we understand that the current rate methodology used for enrollees with ESRD has been in place for a number of years, we believe that there are strong public policy reasons for re-examining its continued use. ESRD-eligible Medicare beneficiaries will have the option to enroll in Medicare Advantage plans for the first time in 2021, and, in light of the relatively high medication costs incurred by those with ESRD—whether or not they are on dialysis—it is at least possible that this option may prove attractive to many of those who will be newly eligible for enrollment in 2021. It is well established that transplantation is more cost effective and more clinically effective for many of those who are on dialysis, and the Trump Administration has taken a serious interest in eliminating regulatory barriers to transplantation under fee-for-service Medicare and encouraging dialysis facilities to refer their patients for transplant evaluation—referrals that historically have been relatively low. Continuing to pay substantially higher rates solely because an ESRD patient is maintained on dialysis provides precisely the wrong financial incentive to Medicare Advantage plans that will soon be enrolling ESRD-eligible Medicare beneficiaries in potentially large numbers.

For this reason, we strongly encourage CMS to consider the feasibility of unifying the ESRD rate structure such that a single basic rate applies to all ESRD-eligible enrollees regardless of whether or not they are on dialysis. The pre- or post-transplantation status of a Medicare beneficiary could be taken into account as one of a number of risk factors, with appropriate risk adjustments for post-transplant patients depending on the quality of the organ they receive and whether the transplant involved is a deceased donor or living donor transplant, all of which can have substantial impact on costs. Since ESRD-eligible Medicare beneficiaries are only eligible for Medicare for three years post-transplant, any potential over-prediction of costs for this patient population necessarily would be time limited.

We appreciate the opportunity to comment on these increasingly important issues and would be pleased to provide additional clinical input into the ESRD rate methodology or other ways to encourage the provision of transplant evaluations for ESRD-eligible Medicare beneficiaries enrolled in MA plans, if you believe that would be helpful.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Dixon Kaufman". The signature is fluid and cursive, with the first name "Dixon" and last name "Kaufman" clearly distinguishable.

Dixon B. Kaufman, MD, PhD
ASTS President



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American Society of Transplant Surgeons

March 5, 2018

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

Re: Centers for Medicare and Medicaid Services (CMS); Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter; ID: CMS-2017-0163-0007

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) 2019 Draft Call Letter (Draft Call Letter). 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. Our comments focus on issues related to the proposed ESRD Rate, Risk Adjustment, and other matters 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.

While we have not previously commented on MA Call Letters, we would anticipate that an increased number of our patients and potential patients may be enrolled in a MA plan beginning in 2021. As we understand it, under current law, only those who are enrolled in a MA plan at the time they develop ESRD are eligible for enrollment in a MA plan. And while Special Needs Plans (SNPs) may enroll Medicare beneficiaries with ESRD, the number of SNP plans is relatively limited. In 2021, however, those eligible for Medicare coverage solely due to ESRD (ESRD-eligible beneficiaries) will have the option to enroll in MA plans, and many may choose to do so.

This expansion has the potential to constitute a “sea change” for ESRD patients and for the MA Program. Medicare is by far the largest payer for those with ESRD, and the great majority of those covered by the program are covered because they have ESRD (ESRD-eligible), rather than being qualified for coverage due to age or disability (Age/Disability-eligible). Thus, for the first time, MA will become available to a large population of those under 65 who

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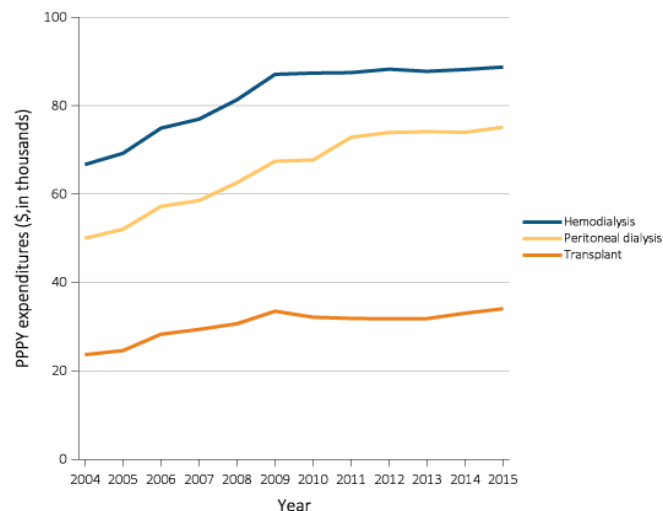
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have no disabilities, and who may be (relatively) healthy compared with many of those traditionally enrolled in MA. This fact has substantial implications for the MA ESRD rate-setting structure and risk adjustment methodology.

We also note that ESRD-eligible beneficiaries may be somewhat more appropriate for transplantation than those eligible for Medicare coverage due to age/disability, since the former group may be somewhat younger and less likely to have multiple other chronic and other serious clinical conditions. Generally, ESRD patients who are clinically appropriate for transplantation are those who are in relatively better health than those who remain on dialysis, and transplantation is more commonly performed among those who are younger than 65. For this reason, the extension of MA eligibility to the ESRD-eligible patient population is of particular interest to the transplant community.

The Benefits of Renal Transplantation

Kidney transplantation is often the best treatment option for Medicare patients with ESRD. The average kidney transplant recipient lives more than twice as long as the average dialysis patient and enjoys markedly improved quality of life. Furthermore, transplantation is the most cost-effective long-term treatment for such patients: The cost difference between a patient on dialysis and a patient who has been transplanted successfully is in the range of \$50,000 per patient per year.



Therefore, transplantation is not only the preferred clinical option for those ESRD patients who meet applicable clinical criteria but is also the most cost-effective option for the Medicare Program.

Renal Transplantation in the Context of MA

Significantly, however, the cost benefits of kidney transplantation accrue in the post-transplant period. For this reason, these savings may not accrue to MA plans that encourage the transplantation of either ESRD-eligible or Age/Disability-eligible beneficiaries. Age/Disability-eligible and ESRD-eligible Medicare enrollees have the option to switch MA plans or opt for Medicare FFS coverage in the post-transplant period, and Medicare coverage for ESRD-eligible beneficiaries in the post-transplant period is limited to three years, which is approximately the time necessary to recoup the cost of the transplant procedure. Since the likelihood that MA plans will benefit financially by encouraging transplantation of

Age/Disability-eligible or ESRD-disabled Medicare beneficiaries is uncertain, it is extremely important that access to transplantation be monitored closely by CMS.

It is worrisome that at least one data source indicates that the number of Medicare patients enrolled in MA plans who receive transplants is substantially lower than the number of transplants predicted by the CMS Hierarchical Condition Risk Adjustment Model. A 2016 study conducted by Avalere found that the CMS model over-predicts the number of Medicare Advantage transplant patients by 15%, and that the difference is statistically significant.¹ We encourage CMS to focus special attention on this issue, especially after 2021 when ESRD-eligible beneficiaries will have the option to enroll in MA plans.

ESRD Rates: Methodological Issues

The Draft Call Letter proposes to use the current basic methodology for determining the unadjusted capitation rates payable to MA plans and SNPs for beneficiaries with ESRD. Specifically, under the current methodology and the one that CMS anticipates will be in effect in 2021, a single state-wide unadjusted capitation rate is provided for any Medicare beneficiary with ESRD who is on dialysis (the ESRD Rate); that 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; and the applicable Age/Disabled Rate would be used thereafter, with certain special risk adjustments.

We are concerned that this tripartite rate methodology calculation has the potential to dis-incentivize renal transplantation. Based on the 2018 rate tables, a SNP or MA plan that enrolls a Medicare patient who has, or who develops, ESRD and is placed on dialysis is paid an unadjusted capitated payment averaging approximately \$6,000-\$8,000 per member per month (\$72,000-\$96,000 per year), and payment at that rate is continued so long as the patient is on dialysis. If the patient is transplanted, this rate is increased for the month of the transplant and for the two subsequent months, using a “transplant factor” that is calculated to compensate the MA plan/SNP for the state average transplant costs. However, after the transplant, the unadjusted capitation payment is reduced to the rate paid for Aged/Disabled members—an average \$800-\$900 per member per month (\$9,600-\$10,800 per year)—approximately one-tenth of the unadjusted capitation rate paid for an ESRD enrollee on dialysis. While the post-transplant capitation rate is eligible for certain special adjustments to account for the beneficiary’s post-transplant status, it is unclear to us whether and to what extent these factors will reduce the differential between the capitation rate paid for enrollees on dialysis and those who have received a transplant, and we believe it likely that, once all adjustments are considered, the risk-adjusted capitation rate paid for an ESRD patient on dialysis will remain substantially higher than the risk-adjusted capitation rate paid for a post-transplant patient, thereby providing an inadvertent (but financially strong) incentive for MA plans to maintain ESRD enrollees on dialysis.

If, in fact, little could be done to reduce the average cost of providing health care services to ESRD enrollees on dialysis below the ESRD rate, the differential between the ESRD capitation rate and the

¹See Avalere Health, “**Analysis of the Accuracy of the CMS-Hierarchical Condition Category Model**” (January 2016) (Avalere Report).

capitation rate paid for post-transplant beneficiaries arguably would not create such a disincentive. However, it appears clear that substantial savings are achievable for at least some ESRD enrollees on dialysis. For example, under the Centers for Medicare and Medicaid Innovation (CMMI) Comprehensive ESRD Care (CEC) model demonstration, each of the demonstration participants reduced the cost of care for ESRD-eligible patients substantially compared with historical benchmarks, and shared in the savings. Therefore, we have every reason to believe that the differential in the capitated rates payable for dialysis and post-transplant patients will create a strong disincentive for MA plans to arrange for the transplantation of clinically appropriate ESRD enrollees.

It is unclear to us whether and to what extent this differential in payment is attributable to the data source used to establish the proposed ESRD rates for patients on dialysis. Specifically, it is unclear to us whether the current and proposed ESRD rates for those on dialysis are computed using cost data for all MC beneficiaries on dialysis (i.e., both ESRD-eligible and Age/Disabled-eligible beneficiaries) or using cost data for the Aged/Disabled-eligible population only. Since per patient costs (and the differential between unadjusted capitated rates for those on dialysis and those who have been transplanted) may be higher if the FFS cost data upon which these rates are determined are limited to the Medicare/Aged-Disabled population, we request that this issue be clarified in the final 2019 Call Letter.²

Regardless of what data is used to determine ESRD rates, we encourage CMS to consider modifying its methodology to account for the substantial range in the health status of ESRD enrollees on dialysis. As indicated above, in and after 2021, the composition of the population of MA enrollees on dialysis may change such that the great majority of this population will be under 65, and those on dialysis will include many younger and healthier ESRD-eligible beneficiaries. While a capitated rate in the range of \$72,000-\$96,000 per year may be appropriate for some of those on dialysis, it is likely to leave quite a bit of room for profit for MA plans that enroll the younger (and potentially healthier) ESRD-eligible patients. A capitated rate of this magnitude has the potential to provide substantial incentive for MA plans to enroll younger, healthier ESRD-eligible MA beneficiaries, for whom the profit margin may be considerable, and to retain them on dialysis rather than encouraging transplantation. On the other hand, we believe it likely that there is a cohort of those on dialysis for whom the ESRD rates proposed will be too low, providing an incentive for MA plans to dissuade MA enrollment.

Under these circumstances, we encourage CMS to consider how the tripartite ESRD methodology should be revised to avoid the establishment of capitation rates that are so substantial as to create strong financial incentives for MA plans to “cherry pick” younger and healthier ESRD-eligible beneficiaries and retain them on dialysis. A number of options might be explored. For example, the ESRD rates for those on dialysis might be subdivided to, at the very least, distinguish between ESRD-eligible beneficiaries and Aged/Disabled enrollees. However, this method would still result in the payment of the same capitation rate for ESRD enrollees with substantially different clinical profiles. It would be somewhat more appropriate to establish separate ESRD rates based on age decile (e.g., under 20 years old, 20-30 years

² We note that the Medicare beneficiaries in non-SNP MA plans are necessarily eligible for Medicare coverage due to age or disability, since the MA option is available only to those who develop ESRD while they are already enrolled in a MA plan. However, it is our understanding that SNP plans may enroll ESRD-eligible as well as Age/Disabled-eligible beneficiaries. Since ESRD-eligible and Age/Disabled-eligible Medicare beneficiaries represent two very different demographic groups, we would have thought that the inclusion of their cost data would reduce the ESRD Rates for SNP plans below the ESRD rates for MA Plans. Since the rates for both MA plans and SNPs are the same, it is unclear to us which ESRD patient population cost data is used to determine ESRD rates.

old, 30-40 years old). An even more granular system would establish different ESRD rates based on Estimated Post Transplant Survival (EPTS) score, which is assigned to all adult candidates on the kidney waiting list and is based on four factors: time on dialysis, diagnosis of diabetes, prior solid organ transplants, and age.³ We believe that most if not all of these factors likely are available in Medicare databases for those on dialysis.

We also urge CMS to modify the ESRD rate structure to enable the ESRD rate and transplant factor to extend for longer than three months. An estimated 25-35% of transplant recipients experience delayed graft function and continue on dialysis. Also, the proportion of patients who continue on dialysis for some period post-transplant varies significantly from one transplant center to another, exceeding 50% for some Transplant Centers' patients. Payment on the basis of the ESRD rate, adjusted using the transplant factor, should continue until the patient no longer requires dialysis.

Finally, in light of the clinical and cost benefits of transplantation, we encourage CMS to consider a system under which unadjusted MA capitation rates are similar for ESRD beneficiaries, regardless of whether they are on dialysis or they have received a transplant within the prior year. Such a system would have the potential to incentivize transplantation for clinically appropriate patients. We recommend that CMS consult with the USRDS, which closely analyzes the Medicare costs attributable to various ESRD treatment modalities, to determine whether to modify the current ESRD rate methodology in a manner that provides similar payment for patients on dialysis and those who have been transplanted (for some defined post-transplant period).

Risk Adjustment

It is unclear to us whether and to what extent the risk adjustment methodology in the Draft Call Letter will exacerbate or reduce the differential between the capitation rates paid for ESRD patients on dialysis and those who have received a transplant, and we strongly suggest that CMS model out the results of the proposed risk adjustment methodology to determine how this differential is likely to be impacted.

Also, we believe that the list of risk factors that have been identified in the 2019 Draft Call Letter is incomplete. Risk factors such as obesity, smoking, protein calorie malnutrition, and poor social situation all negatively affect outcome. Other risk factors relate to characteristics of the organ that is transplanted, such as the "quality of the kidney": the type of graft used, whether the organ is from a deceased or a living donor, and other donor characteristics (e.g., whether the organ is from a standard criteria donor (SCD), an extended criteria donor (ECD), or donation after circulatory death (DCD). Other risk factors include the presence of proteinuria, the age of the donor, and the hemodynamic stability of the donor. Recipient factors include, but are not limited to, recipient factors such as age, cause of renal failure (recurrent disease possibility), HLA compatibility, ethnic background, whether the transplant is a kidney or kidney-pancreas transplant, and time on dialysis. Risk factors in the post-transplant period include but are not limited to cardiac comorbidities, vascular issues, and infection. Notably, even younger ESRD patients who meet transplant eligibility requirements may have severe comorbidities that warrant substantial upward risk adjustment in the post-transplant period.

³ See <https://optn.transplant.hrsa.gov/resources/allocation-calculators/epts-calculator/>. See also <http://transplantmodels.com>.

The Scientific Registry of Transplant Recipients (SRTR) has performed considerable research and analysis of the risk factors relevant to transplantation for the purpose of determining program specific outcomes for transplant centers, which are used by CMS to determine compliance with Medicare certification requirements. We strongly recommend that CMS consult with the SRTR to determine the risk factors that should be taken into account to adjust the transplant factors and in determining payment for during the post-transplant period.

Organ Acquisition

The 21st Century Cures Act explicitly indicates that organ acquisition costs are to be excluded from the MA rate methodology and paid under FFS Medicare. The 2019 Draft Call Letter does not appear to address this issue. Organ acquisition costs can vary substantially and can be significant. We recommend that the 2019 Final Call Letter explicitly indicate that organ acquisition costs are excluded from ESRD rate and direct MA plans to exclude these costs from any contracts that they may negotiate with Transplant Centers. Transplant Centers should be directed to bill these costs directly to Medicare FFS contractors, regardless of whether the patient involved is covered under Medicare FFS or MA.

Because organ acquisition costs can be significant and can vary substantially from one Transplant Center to another—even within the same state—we also request that organ acquisition costs be treated as a pass through cost in 2019 and 2020, years preceding implementation of the 21st Century Cures organ acquisition cost pass-through methodology.

MA Eligibility in the Context of Preemptive Transplantation

We are also concerned that the Call Letter does not address the process to be used by ESRD-eligible beneficiaries to enroll in MA based on the performance of a pre-emptive transplant. The Medicare eligibility of many ESRD-eligible patients is triggered by the performance of a transplant: Their Medicare eligibility starts at the day of transplant with retrospective coverage to cover the transplant work up. This group generally has the lowest ESRD-related costs overall, since they avoid dialysis and vascular access placement. It is not clear to us whether these patients will have the option to elect MA enrollment, and, if so, how that process will work. We request that the Final Call Letter address enrollment processes for this subgroup of ESRD-eligible beneficiaries, including those who opt to receive preemptive transplants. If enrollment is limited to those who have had dialysis, the cost to the system will increase and less positive outcomes can be expected, since time on dialysis is a strong determinant of five-year organ survival.

Immunosuppressant Coverage under Parts B and D

In the context of the Draft Call Letter, we are concerned about two issues related to coverage of immunosuppressive drugs. First, since ESRD-eligible eligibility continues post-transplant only for the purpose of providing coverage for immunosuppressant drugs, we urge CMS to consider how the transition from MA to FFS Medicare is to be handled for those ESRD-eligible beneficiaries who opt for enrollment in an MA plan. The time period immediately leading up to and following a transplant can be extremely stressful, and it is critical that this transition be handled in a manner that ensures no interruption in the provision of immunosuppressive drugs post-transplant.

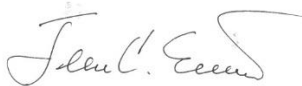
Second, CMS is proposing to use its own data—rather than relying on information from prescribing physicians—to determine whether a Medicare patient’s initial transplant is covered under Medicare Part A. We understand that this determination is critical because immunosuppressant coverage under Part B

is only available if the initial transplant was covered under Part A, and it is only when Part B coverage is unavailable that the beneficiary can get coverage for immunosuppressive drugs under Part D. While we understand and appreciate CMS' concern about the reliability of prescribing physician-reported data, we note that if CMS mistakenly determines that a patient's initial transplant was covered under Part A and the Medicare Part B contractor reaches a contrary conclusion, the patient may be left without coverage of expensive and typically unaffordable but critical immunosuppressant drugs. In fact, the 2019 Draft Call Letter suggests that the agency anticipates that a number of Medicare beneficiaries will be denied Part D coverage of their immunosuppressive drugs if the proposed process for making these determinations is finalized without change. For this reason, if CMS finalizes this proposal, we urge the agency to contemporaneously inform all Medicare Part B contractors of the beneficiary identification numbers of those whose Part D coverage is affected to ensure uninterrupted coverage of immunosuppressive drugs.

We also request that CMS establish data transmittal requirements that ensure that any Medicare beneficiary whose transplant is covered by an MA plan or an SNP plan is transmitted to CMS in a timely manner. Since 21st Century Cures likely will result in an increased number of ESRD-eligible beneficiaries in MA plans and in SNPs, it is critical that MA Plan and SNP data be checked when the Medicare status of the initial transplant is determined.

We appreciate the opportunity to comment on these increasingly important issues and would be pleased to provide additional clinical input into the ESRD rate methodology if you believe that would be helpful.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jean C. Emond". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Jean C. Emond, MD
President