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Submitted Via Regulations.gov

March 5, 2018

Mr. Demetrios Kouzoukas
Principal Deputy Administrator and Director
Center for Medicare

Ms. Jennifer Wuggazer Lazio, F.S.A., M.A.A.A.
Director, Parts C & D Actuarial Group
Office of the Actuary

Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-2017-0163 – 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

Dear Mr. Kouzoukas and Ms. Wuggazer Lazio:

DaVita is pleased to comment on the 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. Our more than 70,800 DaVita Kidney Care teammates care for 197,800 end stage renal disease (ESRD) patients, and we operate or provide administrative services at 2,510 dialysis facilities nationwide. In addition, DaVita serves 2,900 beneficiaries with ESRD under the MA Chronic Condition Special Needs Plan (MA C-SNP) program.

The MA care model squarely aligns with our deep-rooted commitment to improving our patients' quality of life by integrating their care and offering personalized treatment plans. We are proud of our participation in MA ESRD C-SNPs, which allows us to apply not only our significant renal care experience, but also several innovative strategies that address beneficiaries' clinical and social needs. Our performance on key indicators demonstrates the difference our providers have made in helping beneficiaries with ESRD maintain their health. Specifically, compared to United States Renal Data System (USRDS) statistics, the MA ESRD C-SNPs in which we participate have achieved:

- a 25 percent lower hospitalization rate;
- a 51 percent lower hospital readmission rate, significantly reducing the risk of hospital-acquired infections; and
- a 66 percent lower central venous catheter rate.

These results underscore the value that MA plans can bring not only to beneficiaries with ESRD, but also to the overall Medicare program. We are pleased that Congress recognized this value by affording beneficiaries with ESRD the same MA coverage choices as all other beneficiaries beginning in 2021.

DaVita appreciates the work undertaken annually by the Centers for Medicare & Medicaid Services (CMS) to revise the MA payment methodology with the goal of ensuring payment adequacy. However, as CMS knows well, interactions between the methodology's various components can affect attainment of that goal. For example, the projected 5.07 percent increase in the dialysis-only ESRD United States Per Capita Cost (USPCC) better aligns with current cost trends. Yet, the proposed ESRD risk adjustment model recalibration does not appear to be neutral relative to the 2012 model. As a result, the proposed recalibration inappropriately lowers risk scores. Further, the risk score decreases resulting from the proposed recalibration seem inconsistent with CMS's projection of the 2019 ESRD normalization factor, which is 1.8 percent higher than the 2018 ESRD normalization factor under the 2012 model. It is difficult to reconcile the incongruent observations that as the cost trend has increased, risk scores have decreased, and the normalization factor has increased, which calls into question the proposed recalibration's validity and implementation readiness.

To be clear, we strongly support CMS's efforts to ensure that MA continues to evolve; applies cutting-edge benefit design principles; and remains a robust coverage option for Medicare's next generation of beneficiaries. However, in the spirit of MA program stability, we once again encourage CMS to consider the collective impact of Advance Notice and draft Call Letter policies on MA plans, providers, beneficiaries, and CMS's oversight responsibilities. Below we have summarized our recommendations, which primarily address ESRD-related MA payment and other proposals with a particular focus on the recalibration of the ESRD risk adjustment model and the need to treat the cost of calcimimetic drugs appropriately under MA.

MA Payment Methodology

- Conduct additional analysis to validate the ESRD risk adjustment model's recalibration and phase-in the revised risk factors;
- Ensure the accuracy of the ESRD normalization factor starting point;
- Exercise authority not to begin phasing-in the payment condition count model next year;
- Hold encounter data processing system (EDPS) and risk adjustment process system (RAPS) blend percentages at 2018 levels for purposes of determining beneficiary risk scores; and
- Adjust MA payments to ensure the appropriate treatment of calcimimetic drug costs under MA.

MA Program Operations

- Take a measured approach in implementing benefit design flexibility rule changes to mitigate potential discrimination against beneficiaries with higher risk;
- Retain the current out-of-pocket cost (OOPC) threshold and explore other avenues through which MA plans can demonstrate compliance with the meaningful difference rule;
- Finalize the revised interpretation of the primarily health-related standard for purposes of offering supplemental benefits; and
- Continue to move forward in developing SNP-specific network adequacy evaluations to ensure that chronically ill and other vulnerable Medicare beneficiaries have good access to the range of providers involved in their care and can maintain important provider relationships.

Again, DaVita is grateful for CMS's solicitation of stakeholder input on the 2019 Advance Notice and draft Call Letter. Should you have any questions, please do not hesitate to contact me at (202) 478-8188 or at LeAnne.Zumwalt@DaVita.com.

Sincerely,

LeAnne Zumwalt
Group Vice President

2019 ADVANCE NOTICE PROPOSALS

I. Recalibration of the ESRD Risk Adjustment Model

CMS has proposed implementing an updated version of the ESRD risk adjustment model, which it calibrates using the fee-for-service (FFS) ESRD population. As such, the resulting coefficients reflect cost and disease patterns for this subgroup of beneficiaries. Specifically, CMS plans to update the data years underlying the model and update the Medicaid factors to be concurrent with the payment year.

Comment/Recommendation

DaVita agrees that the ESRD risk adjustment model must be as robust as possible. As CMS noted, achieving that goal is particularly important given that all beneficiaries with ESRD will have the opportunity to elect an MA plan beginning in 2021. We applaud CMS's effort to improve the model's predictive ability for both higher and lower risk beneficiaries. That said, in reviewing the 2019 ESRD risk adjustment model's updated factors, we respectfully offer that the revised model may create new issues, while not completely address existing ones. First and foremost, although CMS implied that the proposed 2019 ESRD risk adjustment model results in risk score neutrality relative to the 2012 model, our analysis suggests that overall, it will lower risk scores and MA payments for beneficiaries with ESRD. This outcome runs counter to the recent cost trends evidenced in the 5.07 percent projected increase in the dialysis-only USPCC and will undermine MA payments.

We understand that the ESRD risk adjustment model has not been recalibrated in several years; however, it appears that aspects of the recalibration methodology, coupled with the long interval between calibrations, have introduced serious distortions into the model that must be resolved. We urge CMS to avoid creating unintended consequences for MA plans and beneficiaries with ESRD by postponing the recalibrated model's implementation while it works to address these issues and then phase-in the revised risk factors' application over a three-year period. Our specific concerns with the proposed 2019 ESRD risk adjustment model are outlined in greater detail below.

(1) The 2019 ESRD Risk Adjustment Model Does Not Achieve Risk Score Neutrality Compared to the 2012 Model. First, we want to verify that CMS ensured that the 2019 ESRD risk adjustment model is, in fact, neutral relative to the 2012 model. In the Advance Notice, CMS did not explain whether or not it recalibrated each component of the ESRD risk adjustment model (i.e., dialysis, transplant, and post-graph) separately or collectively. If CMS recalibrated each segment separately, our analysis of 2012 and 2019 risk factors showed the following decreases: three percent to seven percent for dialysis; three percent for transplant; and greater than 10 percent for post-graph. In addition, for any period prior to 2021, the population of ESRD beneficiaries served by MA will not mirror the FFS ESRD population upon which CMS based the recalibration. This point is explored further in the next section.

(2) The CMS Should Conduct Additional Analyses to Validate the 2019 ESRD Risk Adjustment Model's Use for the ESRD Beneficiary Population Enrolled in MA. Although CMS explained that it used 2014 diagnoses from FFS claims data to predict 2015 expenditures, it is not clear if it tested the new model's impact on demographic and comorbidity risk scores for the ESRD beneficiary population enrolled in MA plans relative to the FFS ESRD population. Given current rules governing ESRD beneficiaries' MA eligibility, we believe that further validation of the model prior to its implementation is necessary. As CMS knows, ESRD beneficiaries' MA eligibility significantly differs from other beneficiaries' eligibility and will not change until 2021. At present, unless an MA ESRD C-SNP is available, a beneficiary diagnosed with ESRD – regardless of age – currently cannot switch from FFS to MA. However, an MA enrollee eligible for Medicare based on age who subsequently develops ESRD can remain enrolled in the MA plan. As a result, the vast majority of the estimated 95,000 MA ESRD enrollees are likely aged 65 years or older. In contrast, 51 percent of FFS ESRD beneficiaries are aged 65 or older. [1] The fundamental difference in age distribution between these populations also can influence other risk factors. As such, the recalibration of key risk factors such as age, eligibility category (i.e., aged versus disabled), dual eligibility status, and disease comorbidities, may result in risk factors appropriate for FFS ESRD beneficiaries, but could produce inaccurate cost predictions, and thus inadequate reimbursement, for MA-enrolled ESRD beneficiaries.

(3) The 2019 ESRD Risk Adjustment Model Must Rebalance Scores More Evenly. The proposed model appears to result in disproportionately improved reimbursement for the smaller subset of beneficiaries receiving dialysis with the highest risk, while reducing reimbursement for the much larger beneficiary population receiving dialysis, who have average and lower risk. Ideally, the recalibration would result in more balanced reimbursement for high-risk and low-risk beneficiaries. Rather, the proposed demographic ESRD risk factor values presented Table V-6 of the Advance Notice show a meaningful decline compared to the 2012 model. For females and males aged 45 and over, the declines range from seven percent to 13 percent with a simple average demographic risk factor change of -0.06, and from nine percent to 19 percent with a simple average risk factor change of -0.09, respectively (Figures 1 and 2). According to the USRDS, these individuals account for 84 percent of the ESRD population.

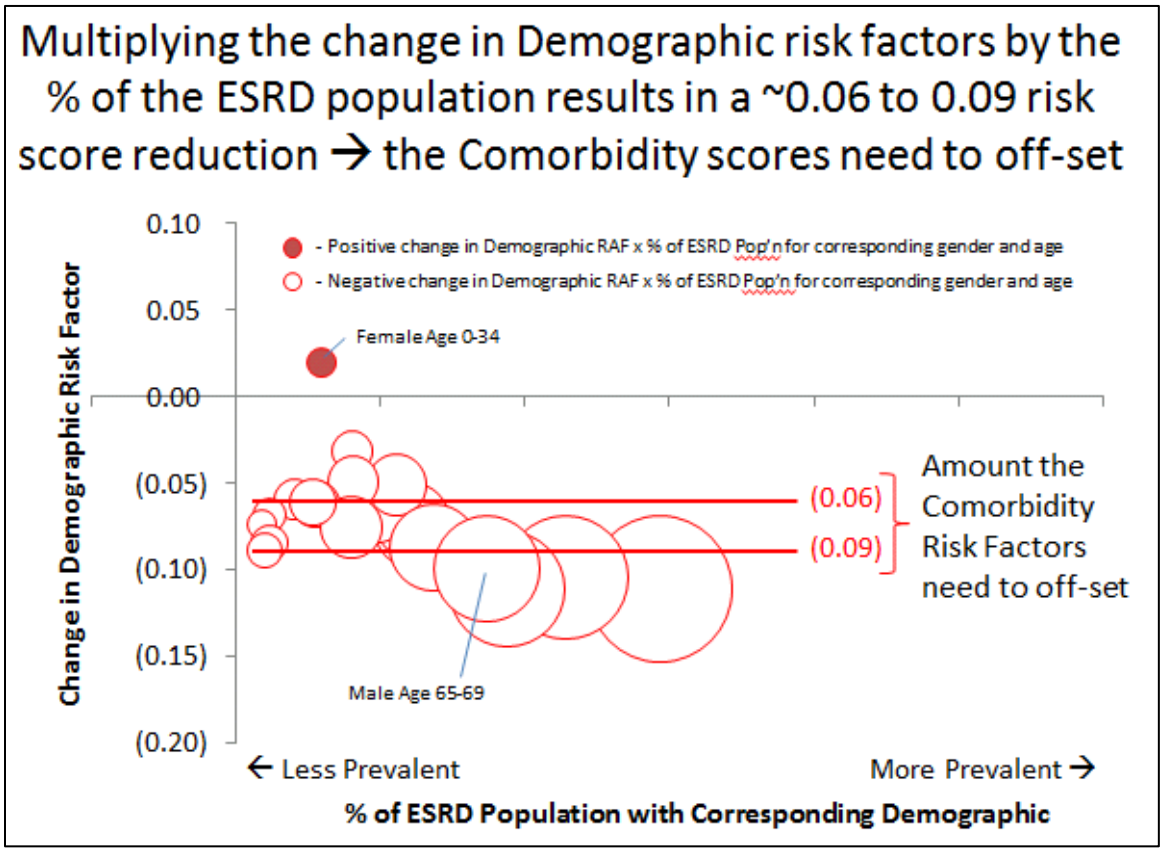
[1] Medicare Payment Advisory Commission (MedPAC), "*A Data Book: Health care spending and the Medicare program*," June 2017.

Figure 1: Comparison of 2012 and 2019 ESRD Risk Adjustment Model Risk Factors by Gender and Age Group

	Females				Males			
	Risk Factor By Model Year		Change		Risk Factor By Model Year		Change	
Age Group (years)	2012	2019	%	Absolute	2012	2019	%	Absolute
45-54	0.598	0.522	-12.7	(0.08)	0.589	0.478	-18.8	(0.11)
55-59	0.606	0.535	-11.7	(0.07)	0.599	0.495	-17.4	(0.10)
60-64	0.619	0.553	-10.7	(0.07)	0.609	0.498	-18.2	(0.11)
65-69	0.686	0.635	-7.4	(0.05)	0.661	0.562	-15.0	(0.10)
70-74	0.702	0.653	-7.0	(0.05)	0.686	0.611	-10.9	(0.08)
75-79	0.717	0.658	-8.2	(0.06)	0.695	0.634	-8.8	(0.06)
80-84	0.739	0.671	-9.2	(0.07)	0.736	0.652	-11.4	(0.08)
85+	0.745	0.671	-9.9	(0.07)	0.752	0.663	-11.8	(0.09)
Simple average absolute change 45+:				(0.06)				(0.09)

Source: DaVita analysis of CMS data

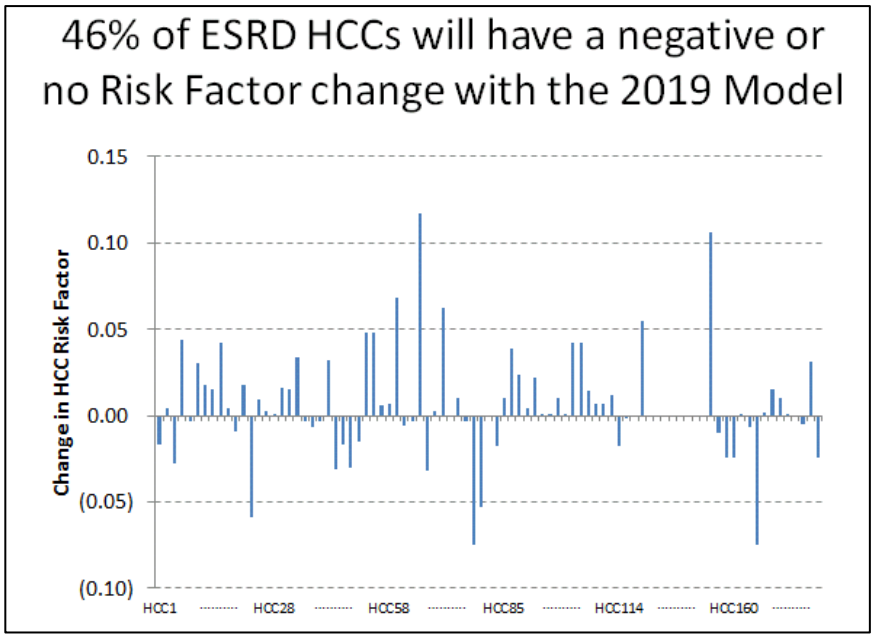
Figure 2: Reduction in Average Risk Score with Demographic Factor Change



Source: DaVita analysis of CMS data interpolated with internal data

Maintaining neutrality in risk score changes would require an equivalent increase in the comorbidity and disease/disabled-disease interactions. However, our analysis of these proposed risk factors compared to the 2012 model's risk factors showed that risk factors for 47 HCCs (54 percent) increased, while risk factors for 40 HCCs (46 percent) decreased or did not change. Risk factors that increased have a simple average increase of 0.024, while those that decreased have a simple average decrease of -0.021 (Figure 3). This implies that the typical MA ESRD enrollee will not likely see an increase in their comorbidity risk factor significant enough to offset the steep demographic risk factor decline.

Figure 3: Change in Risk Factors by HCC under 2019 ESRD Risk Adjustment Model Relative to 2012 ESRD Risk Adjustment Model



Source: DaVita analysis of CMS data

In addition, risk factor changes for certain HCCs do not necessarily align with comorbidity and treatment patterns for beneficiaries with ESRD. For example, HCC 73 (Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease) and HCC 76 (Muscular Dystrophy), which are not very common, experienced relatively larger risk factor increases of 0.12 and 0.06, respectively. In contrast, the risk factor for HCC 22 (Morbid Obesity), which is more common and usually associated with health complications for beneficiaries with ESRD, and thus additional costs, decreased by -0.06 or -45 percent. These seemingly selective risk factor adjustments suggest that the recalibration will focus more on rewarding MA plans that serve ESRD patients whose diagnoses map to more HCCs or who have rarer conditions, rather than the complexity and prevalence of a particular comorbidity.

To assess this issue more thoroughly, we compared risk factor changes under the CMS-HCC model 2014 community segment and the 2017 community segment for non-dual eligible aged beneficiaries to the risk factor changes observed between the 2012 and 2019 ESRD risk adjustment models. Under each model, some HCCs, such as HCC 19 (Diabetes Without

Complications) showed similar decreases in risk factors. For other HCCs, the risk factor decreases under the ESRD model were significantly higher, rather than proportional to decreases under the CMS-HCC model community segment (Figure 4). These results are counterintuitive and further illustrate the need to reassess the implementation of the proposed ESRD model's recalibration.

Figure 4: Comparison of Percent Change in Risk Factors for Select HCCs Under Revised Risk Adjustment Models

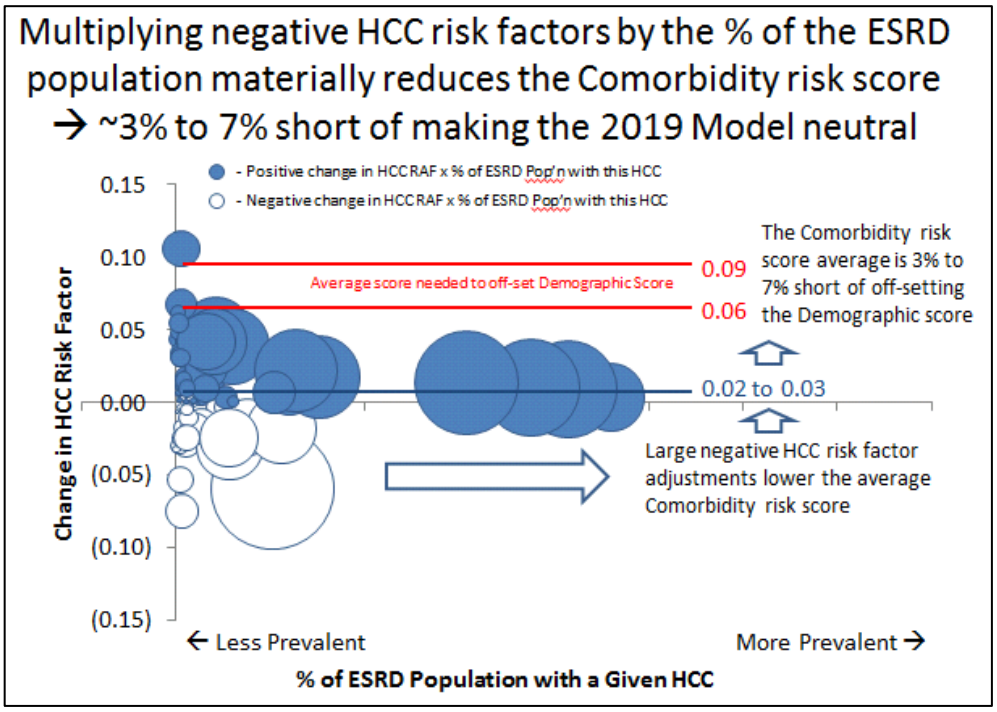
	Percent Change in Risk Factor	
	2014 Community v. 2017 Community Non-Dual Aged	**2012 v. 2019 ESRD Model**
HCC 19 Diabetes Without Complications	-11.9	-12.0
HCC 22 Morbid Obesity	-25.2	-44.7
HCC 84 Cardio-Respiratory Failure and Shock	-8.2	-29.0
HCC 48 Coagulation Defects, Other Specified Hematological Disorders	-12.3	-22.4

Source: DaVita analysis of CMS data

To validate these observations and since DaVita does not have access to the 2014 data and HCC percentages CMS applied in recalibrating the model, we used other sources to estimate required comorbidity risk factor average scores necessary to offset the demographic risk factor declines and ensure the 2019 model's neutrality. After estimating the number of HCCs the average MA ESRD enrollee has, we calculated the simple and weighted average HCC risk factor improvement between the 2012 and 2019 models using our own data. Based on these internal estimates, an MA plan would need to have beneficiaries with approximately two to three additional HCCs than its current enrollment to offset the average -0.06 female ESRD demographic risk factor reduction and approximately three to 4.5 additional HCCs than its current enrollment to offset the average -0.09 male ESRD demographic risk factor reduction. Absent this offset, the resulting average comorbidity risk factor score falls short of offsetting the demographic risk factor score (Figure 5).

In conclusion, our analysis indicates that for the majority of beneficiaries with ESRD, the 2019 model will produce a significant decrease in the risk scores attributable to the demographic risk factor decline, while increasing risk scores for only a very small segment of beneficiaries with ESRD who have high HCC counts. The result is a net decrease in nearly all circumstances. Given these outcomes and the destabilizing effect they will have on MA plans and beneficiaries with ESRD, DaVita urges CMS to temper the model recalibration or focus the recalibration only on comorbidities and not include demographic risk factor changes. Postponing implementation of a new ESRD risk adjustment model until CMS has had the opportunity to validate the results on the existing MA ESRD population and made any necessary adjustments, then phasing-in the revised risk factors, will increase stakeholders' confidence in the model when MA eligibility rules change for beneficiaries with ESRD in 2021.

Figure 5: Gap in Comorbidity Risk Score and Demographic Factor Change



Source: DaVita analysis of CMS data interpolated with internal data

(4) 2019 Model Results in Inadequate Reimbursement for Kidney Transplants. The proposed model further undermines the adequacy of reimbursement for kidney transplant costs by decreasing the three-month ESRD Kidney Transplant risk factor total from 7.823 to 7.554, a 3.4 percent reduction. Furthermore, it is not clear if CMS only used MS-DRG 652 (Single Kidney Transplant) to identify the kidney transplant event or if it also used this single DRG to calculate kidney transplant costs. If CMS took the latter approach, the result would underestimate transplant reimbursement by excluding costs associated with multi-organ transplants that include kidneys. As CMS knows, many of these multi-organ transplants have DRGs with costs that exceed, in some cases by more than double, the costs associated with MS-DRG 652. Reducing the total risk score for kidney transplants will make it more challenging for MA plans to develop robust kidney transplant provider networks.

(5) 2019 Model Will Exacerbate Challenges Stemming from Inadequate Reimbursement for Kidney Organ Acquisition Costs (OACs). As CMS knows, MA plans incur separate costs to acquire donor kidney organs. These costs, which are substantial, are not reimbursed through the ESRD Kidney Transplant rate, which makes it difficult for MA plans to develop broader kidney transplant provider networks. DaVita appreciates that Congress established a separate payment for kidney OACs beginning in 2021. However, until then, MA plans will continue to face reimbursement challenges since the proposed three-month ESRD Kidney Transplant risk factor total still does not include OACs. Implementation of the proposed 2019 ESRD risk adjustment model will exacerbate those challenges.

II. Normalization Factor for the ESRD Dialysis Risk Adjustment Model

Under ESRD risk adjustment model, CMS applies a normalization factor to adjust for differences in risk scores between the model's denominator year and the payment year. The normalization factor's application is also intended to help stabilize payments between risk adjustment model calibrations.

Comment/Recommendation

In the 2018 Advance Notice, CMS proposed an ESRD normalization factor that significantly deviated from prior years' factors and would have inappropriately decreased MA payments for beneficiaries with ESRD. DaVita is grateful that CMS considered stakeholders' concerns and finalized a normalization factor more consistent with current trends. We appreciate that CMS proposed continuing to apply the linear methodology rather than the quadratic functional form methodology in deriving the 2019 ESRD dialysis model normalization factor.

In the 2019 Advance Notice, CMS indicates that it used risk scores based on the proposed 2019 ESRD risk adjustment model to determine the proposed ESRD dialysis normalization factor. Based on our analyses regarding the proposed ESRD risk adjustment model recalibration presented above, the ESRD Dialysis Model value of 1.000 for 2015 appears to be incorrect, particularly as it applies to an MA ESRD population, which is demographically distinct from the FFS ESRD population. Instead, unless CMS addresses the lack of risk score neutrality between the 2012 and 2019 models, a 2015 starting value that reflects the 2019 model's downward impact on risk scores – that is, a starting value three percent to seven percent lower compared to the 2012 model, or 0.930 to 0.970, would be more appropriate (Figure 5). With a lower 2015 risk score, instead of the proposed 1.000 value, the implied 2019 ESRD dialysis normalization factor would be in the range of 0.961 to 1.002.

Figure 5: Normalization Factor Start Values

		Projected	
Data Source	**ESRD Dialysis Model 2015 Start Value**	**2018**	**2019**
As CMS proposes	1.000	1.025	1.033
If 2019 recalibration is 3% lower	0.970	0.994	1.002
If 2019 recalibration is 7% lower	0.930	0.953	0.961

Source: DaVita analysis of CMS data

III. Guidance on Calcimimetic Drug Coverage and Payment to MA Plans

Under current law, CMS will cover and pay for ESRD oral-only drugs and biologics under the Medicare Part D prescription drug benefit until 2025, at which time, it will incorporate payments for these drugs into the ESRD bundle. Current law also stipulates that introduction of an intravenous (IV) form of an oral ESRD drug or biologic triggers the oral form's shift from Part D, such that Part B will reimburse for both drug forms. As CMS knows, the introduction of Parsabiv, an IV calcimimetic resulted in CMS reimbursing for both Parsabiv and Sensipar, an oral calcimimetic, under Part B beginning January 1, 2018. CMS has established a two-year transitional add-on payment policy to afford sufficient time to gather utilization data prior to fully incorporating payment for the drugs into the ESRD bundle.

Comment/Recommendation

With the shift in coverage from Part D to Part B, MA plans are now financially responsible for paying dialysis facilities for calcimimetic drugs under Part C. It is our understanding that during a conference call with MA plan representatives, CMS has instructed MA organizations to include these costs in their 2019 bids. To ensure the even application of coverage and reimbursement requirements across MA plans, DaVita along with several other stakeholders on multiple occasions have respectfully requested that CMS provide definitive policy guidance on this issue. In finalizing the 2018 ESRD Prospective Payment System (PPS) rule last November, CMS noted it received comments on this topic and stated its intent to issue guidance "soon." DaVita was hopeful that CMS would take the opportunity presented by the 2019 MA Advance and Final Notice process to follow through on that intent. We urge CMS not to delay any longer to avoid compromising beneficiaries' access to these important medicines and creating any unnecessary confusion among MA plans and dialysis providers. Below we reiterate our recommendations submitted in previous comment letters.

(1) Revisit and Reissue the 2011 Guidance Regarding ESRD-Related Drugs and MA Plan Coverage and Payment Obligations. As a general rule, MA plans are not required to pay dialysis facilities in accordance with the ERSD PPS methodology, but they are required to cover and pay for the full scope of benefits offered under Parts A and B.[2] This means that when an ESRD-related drug transitions from coverage under Part D as an oral-only drug to coverage under Part B with both oral and IV forms, the MA plan must assume responsibility for coverage and payment of that drug under Part C. CMS reiterated the regulatory requirements[3] in its 2011 sub-regulatory guidance, stating:

This change in the original Medicare payment for renal dialysis services also represents a change in coverage for ESRD-related drugs from Part D to B…[meaning] that ESRD-related drugs now covered under Part B must be covered under the Part C portion of [the MA-PD plan's] bid, rather than the Part D portion.. [4]

With oral and IV calcimimetics covered under Part B as of January 2018, the failure of an MA plan to acknowledge and pay for these drugs under Part C would violate CMS's regulations.[5] It also would violate CMS's standard MA contract provisions, which reiterate the MA plan's obligation to pay for all basic benefits offered under Parts A and B.[6]

Calcimimetics represent a critical element of dialysis treatment and are materially more expensive than other ESRD-related drugs that previously have transitioned from Part D to Part B coverage. CMS should issue written guidance to MA plans now reminding them of their financial obligation for oral and IV calcimimetics. As part of that written guidance, CMS should clearly express its expectation that MA plans provide fair and adequate reimbursement to dialysis facilities for the calcimimetic drugs.

(2) Adjust Payments to MA Plans to Account for Financial Responsibility for Calcimimetics. Given that CMS uses historical Parts A and B data, the 2019 MA benchmarks will not reflect spending on these calcimimetics. Although we understand that eventually,

[2] 42 C.F.R. §§ 422.100(c), 422.101(a).

[3] 42 C.F.R. §§ 422.109(b).

[4] CMS Health Plan Management System (HPMS) Guidance: *Clarification of Exclusion of Part D Payment for Drugs Included in the End-Stage Renal Disease Prospective Payment* (May 5, 2011).

[5] *Id.*

[6] 42 C.F.R. § 422.504(a)(3)(i); Medicare Managed Care Manual, Ch. 11, § 100.1.

expenditures on calcimimetics will be incorporated into the MA benchmark calculations, these drugs are among the costliest drugs that have shifted from Part D to Part B. As such, the lag time presents unique and significant challenges. For example, CMS already directly pays a substantial portion of calcimimetics' costs since many beneficiaries who take them reach Part D's catastrophic coverage threshold. In contrast, MA plans bear full fiscal responsibility for Part B drugs. Depending on several factors, these circumstances may or may not present a financial hardship for MA plans. For example, the shift in the oral drug's coverage may have less impact on larger MA plans and those with fewer ESRD enrollees; however, the impact on MA ESRD C-SNPs will be substantial.

Under current law, CMS must adjust MA capitation rates or make other payment adjustments to account for newly-covered items and services under a National Coverage Determination or a legislative change in benefits when the item or service represents a significant cost.[7,8] If an item or service meets the significant cost threshold, then the MA plan does not have to assume risk for the costs of that item until CMS appropriately adjusts its capitated payments to the MA plan to account for the cost, likely in the next fiscal year.[9] Instead, in such circumstances, the supplier furnishing the item receives payment directly from the *Medicare fee-for-service contractor* under "original Medicare payment rules, methods, and requirements."[10]

Although we do not know the complete details of CMS's methodology, based on available information on drug costs and national average per capita costs, we believe the significant cost threshold will be met. Even if that threshold is not met, given the unique circumstances, CMS should explore other avenues of authority to provide supplemental payments to MA plans for calcimimetics. Applying a payment adjustment will ensure that cost considerations do not influence MA enrollees' access to these important drugs or limit their ability to avail themselves of a Medicare coverage choice that best meets their needs.

IV. Incorporation of 21st Century Cures Act (P.L. 114-255) Policies and Other Updates into the CMS-HCC Risk Adjustment Model

The 21st Century Cures Act (P.L. 114-255) requires CMS to improve the CMS-HCC risk adjustment model in 2019 and subsequent years. Specifically, the law directs CMS to: (1) evaluate the impact of including additional diagnoses related to mental health, substance abuse, and the severity of chronic kidney disease (CKD); (2) account and adjust for a beneficiary's total number of diseases and conditions; and (3) phase-in risk adjustment model changes over a three-year period. To comply with the law, CMS has proposed adding four HCCs, including HCC 138 (CKD Moderate Stage 3); incorporating select drug and alcohol poisoning codes into an existing HCC to create a new HCC 55; and introducing a new factor into the six community and single long term institutional (LTI) segments to account for a beneficiary's number of conditions. CMS also has proposed updating the years used to calibrate the CMS-HCC model and applying the same approach used to filter encounter data records in selecting 2014 diagnoses for the calibration and increasing the encounter data-based portion of beneficiary risk scores to 25 percent in 2019.

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[7] *See,* 42 U.S.C. § 1395w-23(c)(7); 42 C.F.R. § 422.308(g); 42 C.F.R. § 422.109; Medicare Managed Care Manual, Ch. 8, § 40.4; Medicare Managed Care Manual, Ch. 4, § 90.3.

[8] 42 C.F.R. § 422.109(a).

[9] 42 C.F.R. § 422.109(b) and (c).

[10] *Id.* at § 422.109(c)(1).

Comment/Recommendation

DaVita wholeheartedly agrees that risk adjustment is central to the MA program's success. Although the CMS-HCC model represents a vast improvement over prior demographic-only models, there is room to augment its predictive ability. We appreciate CMS's previous efforts to address the model's shortcomings and strongly support moving forward in incorporating additional mental health and substance abuse diagnoses and restoring HCC 138 (CKD Moderate Stage 3) next year. However, as explained in our comments below, we have concerns regarding the implementation timeline for the proposed payment condition count model and increase in the encounter data-based portion of beneficiary risk scores.

(1) Implementation of Payment Condition Count Model: DaVita appreciates the thorough explanation of the analysis that CMS undertook in developing the proposed payment condition count model. Although we understand that CMS has shared information with MA plans, they may need additional time and CMS feedback to fully assess the model's impact. CMS's plan to use encounter data in developing the payment condition count portions of beneficiary risk scores introduces another level of uncertainty for MA plans. As CMS noted in the Advance Notice, the statute provides for a three-year phase-in of the risk adjustment model changes over a four-year period. We agree with CMS's interpretation that the statute affords the opportunity to use the 2019 Advance Notice to collect and process comments and reconsider options for 2020. We urge CMS to consider adopting that approach.

(2) Use of Encounter Data Payment System (EDPS) in Determining Risk Scores: DaVita remains concerned about CMS's decision to move forward in using encounter data as a diagnosis source to calculate beneficiary risk scores. As expressed in our comments on prior Advance Notices, the collection and submission of encounter data runs counter to the goals of risk-based payment methodologies. Rather than affording providers the opportunity to focus on care delivery and effective disease management, encounter data reporting forces them back into a FFS payment paradigm. More disconcerting, encounter data fail to capture the breadth of services and activities, such as development and implementation of personalized care plans, which providers in integrated care models apply to help patients reach their treatment goals. As a result, using encounter data for payment purposes will undervalue and undercompensate care.

In addition, although some improvement in encounter data's completeness and reliability may have been achieved since its first use, we question that it is sufficient to warrant a 10-percentage point increase in the EDPS-based portion of beneficiary risk scores. The fact that CMS proposed supplementing encounter data with inpatient diagnoses obtained from RAPS data underscores our concerns about the overall completeness of encounter data.

Given the other risk adjustment model proposed changes, along with the demonstrated negative impact that EDPS has on risk scores and payments, we reiterate our recommendation that CMS hold the 2018 EDPS and risk adjustment payment system (RAPS) blend percentages constant indefinitely. CMS also should develop a uniform industry-wide adjustment – applied retrospectively to years 2016 to 2018 and then prospectively – to offset the inappropriately reduced MA payments that result from the use of encounter data.

DRAFT CALL LETTER PROPOSALS

I. Medicare Advantage Uniformity Flexibility

In the November 2017 MA proposed rule (MA proposed rule), CMS described its determination that providing access to services tied to health status or a disease state coincides with statutory and regulatory benefit uniformity provisions. CMS stated that it was considering issuing guidance for the 2019 contract year clarifying an MA plan's ability to offer medically vulnerable beneficiaries targeted supplemental benefits, provided the beneficiaries meet specific medical criteria and the MA plan treats all similarly situated beneficiaries in the same manner. The 2019 draft Call Letter reiterates the policy presented in the MA proposed rule and states CMS's intent to establish a mailbox following issuance of the Final Call Letter, such that MA plans can pose questions regarding the design and offering of targeted supplemental benefits.

Comment/Recommendation

As stated in our comment letter on the MA proposed rule, DaVita agrees that condition-specific benefits, such as additional preventive services and lower cost sharing, hold great promise for improving outcomes and value for beneficiaries and Medicare. We support adoption of Value-Based Insurance Design (VBID) principles under MA; however, implementing a revised uniformity requirement in the upcoming contract year raises important timing and other practical issues. For example, in the press release accompanying the MA proposed rule, CMS stated it would provide operational details of the policy in the call letter. We understand that CMS currently is reviewing comments and finalizing the MA proposed rule, which may have precluded its ability to provide additional information in the draft Call Letter. That said, since the proposed policy departs significantly from the current, long-standing interpretation, we are concerned that MA plans and other stakeholders will have little opportunity to process the operational guidance prior to its implementation next year. Moreover, it is unclear how the proposed policy interacts with Section 50322 of the Bipartisan Budget Act (BBA) of 2018 (P.L. 115-123), which appears to establish authority to waive the uniformity requirement when offering chronic condition-tailored benefits beginning with the 2020 plan year.

Pending resolution of that issue, we urge CMS to consider a measured approach in implementing the policy by setting initial limits on the number of targeted conditions and tailored benefit packages that an MA plan can offer. As MA plans and CMS gain more experience with a condition-specific tailored benefits policy, CMS could revisit those limits. In addition, the draft Call Letter reiterates the MA proposed rule's language that would require MA plans to use objective and measurable medical criteria to identify eligible beneficiaries. The operational guidance should clarify the party responsible for establishing the criteria. Initially applying CMS-defined criteria, as done under the MA VBID demonstration, would support consistent and fair practices among all MA plans. At the same time, CMS could expand the conditions for which CMS-criteria currently exist to ensure that MA plans throughout the country can align conditions selected for targeted benefits with the needs of their enrollees. CMS could subsequently allow MA plans to develop and apply their own criteria and select other conditions to target. Any plan-developed criteria applied under a revised uniformity requirement also must comply with clear CMS guidelines on acceptable data sources.

In addition, CMS should consider the interactions between a revised uniformity policy and other proposals, such as those to allow variations in benefits by service area segments and eliminate the

meaningful difference standard. Although CMS does not expect a significant increase in the number of MA plans should it finalize the policies, MA plan designs will undoubtedly become more complex through their combined effect. As a result, along with current protocols, such as attestation requirements and in-depth benefits' reviews, the operational guidance must clearly delineate CMS's strategies to ensure that MA plans do not use network designs and other plan features to introduce subtle forms of discrimination.

For example, as CMS knows well, MA plans in recent years have been narrowing their provider networks, which, by undermining long-standing provider relationships, can be problematic for beneficiaries with a chronic illness. DaVita welcomes CMS's recently announced plans to conduct triennial network reviews and is hopeful the process will spur MA organizations to rectify any provider network and directory deficiencies. In our view, the potential for discrimination under a revised uniformity requirement – whether intentional or not – warrants subjecting provider networks under MA plans offering condition-specific benefits to a higher level of scrutiny on an annual basis. In addition to the Government Accountability Office (GAO) study included in Section 50322 of the BBA of 2018, CMS also could consider conducting and releasing an analysis its own analysis of condition-specific plans that identifies best practices and allows stakeholders to understand their impact on quality, beneficiary satisfaction, and access to providers. Finally, in the spirit of transparency, CMS should develop and issue a frequently asked questions (FAQs) document based on the questions about tailored benefits submitted by MA plans to the mailbox that CMS will establish for that purpose.

II. Segment Benefits Flexibility

CMS currently interprets the statute to permit variations in premiums and cost sharing amounts by service area segment (i.e., a county) if the variations are uniform throughout each service area segment. CMS is revising its interpretation such that MA plans could vary supplemental benefits, in addition to premiums and cost sharing amounts, by segment.

Comment/Recommendation

The current segmentation policy has expanded beneficiaries' coverage options, particularly in service areas with wide variation in county benchmarks. The policy also affords CMS and MA organizations a level of administrative simplicity. DaVita agrees that additional benefit design flexibility can help MA plans better meet their enrollees' needs; however, as we expressed in our response to the MA proposed rule, the revised interpretation seems to go far beyond the current policy's intent to enhance MA plans' ability to align their costs with payments. In effect, the revised policy appears to permit MA organizations to use the service area segmentation process to establish county-level plans. Neither the MA proposed rule nor draft Call Letter address the intersection between CMS's revised interpretation and other policies, such as determinations of low enrollment or cross-walking enrollment when a plan is segmented. If benefits differ by segment, it is unclear how and if these policies should apply.

III. Meaningful Differences in MA Bid Submissions and Bid Review

MA organizations may submit – and CMS will approve – bids for multiple plans in the same area under the same contract only if those plans differ substantially from one another based on CMS's annual meaningful difference evaluation standard. The draft Call Letter reiterates CMS's intent to discontinue the meaningful difference requirement beginning with the 2019 contract year MA bid submissions, which it first described in the MA proposed rule.

Comment/Recommendation

As we stated in our comments on the proposed MA rule, we are not completely confident that wholesale elimination of the meaningful difference rule is prudent, especially given the other proposed changes to benefit flexibility rules. As CMS noted in the MA proposed rule, many beneficiaries find it challenging to assess their coverage options. When faced with multiple options, some beneficiaries may become so overwhelmed that they simply give up and forgo a coverage choice that better meets their needs. Although the out-of-pocket cost (OOPC) model does not capture all plan aspects, the current meaningful difference standard helps many beneficiaries narrow their choices, allowing them to spend more time reviewing other plan features, such as provider networks and coverage conditions. A thorough understanding of these features is important to making informed coverage decisions, particularly for beneficiaries with chronic conditions. We encourage CMS to retain the current standard and explore other avenues, such the Medicare Payment Advisory Commission's (MedPAC) recommendation to allow MA plans that fail to meet the OOPC threshold to demonstrate a meaningful difference by submitting other supporting materials.

IV. Health Related Supplemental Benefits

Current rules define a supplemental health care benefit as an item or service: (1) not covered by Original Medicare; (2) that is primarily health-related; and (3) for which the MA plan must incur a non-zero medical cost. To meet the primarily health-related standard, the primary purpose of an item or service must be to prevent, cure, or diminish an illness or injury. CMS has not previously allowed an item or service to be eligible for coverage as a supplemental benefit if its primary purpose is daily maintenance. In the draft Call Letter, CMS announced its intent to expand the scope of the primarily health-related supplemental benefit standard such that an item or service must diagnose, prevent, or treat an illness or injury; compensate for physical impairments; act to ameliorate the functional/psychological impact of injuries or health conditions; or reduce avoidable emergency or healthcare utilization.

Comment/Recommendation

DaVita appreciates CMS's decision to broaden the primarily health-related supplemental benefits standard. This reinterpretation better aligns with the wide body of research demonstrating the value of items and services that do not meet the current standard in helping beneficiaries maintain their health. As CMS knows, beneficiaries with ESRD often experience a number of comorbidities. Managing or preventing these comorbidities depends on a several factors, including monitoring weight gain and loss to assess fluid retention. Like the fall prevention device example cited in the draft Call Letter, providing an ESRD patient with an in-home scale can have a significant, positive impact on their health outcomes.

CMS currently permits MA plans to cover scales for enrollees with congestive heart failure (CHF) and liver disease under the dual purpose policy for over-the-counter (OTC) items and services. We encourage CMS to extend that policy to scales provided to ESRD patients. In addition, we recommend that CMS finalize the revised primarily-health related standard, which will afford MA plans another avenue to ensure that they can design and offer supplemental benefits that meet their enrollees' needs. In doing so, we urge CMS not to create significant administrative barriers that make it challenging for MA plans to offer, and beneficiaries to take advantage of, benefits covered under

the revised standard. For example, under the dual purpose requirements for an OTC item or service, the item or service can be purchased after a provider and beneficiary discuss the purchase or satisfy other requirements an MA plan may specify. This requirement can be met through a written note from, or verbal discussion with, the provider.

V. Special Needs Plan (SNP)-Specific Networks Research and Development

In the 2018 Final Call Letter, CMS announced plans to move forward in developing SNP-specific network adequacy evaluations. The 2019 draft Call Letter stated that CMS is continuing to examine the need for SNP-specific network adequacy evaluations.

Comment/Recommendation

DaVita supports the development of SNP-specific network adequacy evaluations. As CMS knows, Congress authorized SNPs to allow plans to develop, apply, and focus their specific care delivery expertise in serving chronically ill and other vulnerable Medicare beneficiaries. Many patients with a chronic illness and those who are dual eligible often have long-standing provider relationships. They also often face barriers, including lack of transportation that can undermine their ability to adhere to treatment recommendations. Finally, their care often involves a team of providers who focus on the beneficiary's primary condition as well as various comorbidities. For example, on a routine basis, a beneficiary with ESRD will likely see not only a nephrologist, but also a cardiologist, pulmonologist, and vascular surgeon. Subjecting SNPs to more specific network adequacy evaluations will ensure that they continue to fulfill their promise in delivering high-quality care and more important, that the chronically ill and vulnerable beneficiaries they serve have good access to high-value providers.