500 North Capitol Street, NW
Suite 300
Washington, DC 20001
Tel: 202.478.8184 Fax 202.639.0751
www.davita.com

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Submitted electronically via regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-4182-P "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-For-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program"

Dear Administrator Verma:

DaVita welcomes the opportunity to comment on the proposed rule issued by the Centers for Medicare & Medicaid Services (CMS) that revises Medicare Advantage (MA) and Prescription Drug Program (PDP) regulations to promote benefit design and care delivery innovations and reflect enactment of the Comprehensive Addiction and Recovery Act (CARA) and the 21st Century Cures Act.

Our 65,000 DaVita Kidney Care teammates care for 196,000 end stage renal disease (ESRD) patients, and we operate or provide administrative services at 2,470 dialysis facilities nationwide. Many of our patients, especially those who are dually eligible (DE) for Medicare and Medicaid, are among the sickest and frailest of all beneficiaries. Each day, our teammates strive to improve our patients' quality of life by integrating care and offering personalized treatment plans that address their clinical and social needs. We know first-hand that strategies, including sophisticated health management programs and team-based care, are key components of successful approaches to achieving better outcomes and value for our patients.

DaVita strongly supports the work to transform Medicare from a program that largely rewards service volume to one that better aligns financial incentives; meets beneficiaries' changing health care needs; and promotes greater patient engagement. The MA program and its predecessors have demonstrated the importance of risk-based payments to meeting those objectives and informed development of new payment models applied under fee-for-service (FFS). Additional benefit design flexibility and other policy modifications can help ensure that along with FFS, the MA program continues to evolve; applies cutting-edge benefit design principles; and remains a robust coverage option for Medicare's next generation of beneficiaries.

We are grateful to CMS for affirming that the proposed changes to MA plan design rules must not compromise long-standing, fundamental beneficiary protections against discrimination. Strongly enforcing those protections will help ensure that MA organizations do not use benefits and other plan features to discourage enrollment among beneficiaries who may benefit most, including those with ESRD, who Congress granted the same MA choices as other beneficiaries beginning with the 2021 contract year. As always, DaVita appreciates CMS's solicitation and consideration of stakeholder feedback. In addition to the recommendations on benefit design flexibility, our comments focus on the proposed rule's enrollment- and marketing-related provisions. Should you have any questions, please do not hesitate to contact me at (202) 639-0750 or LeAnne.Zumwalt@DaVita.com.

Sincerely,

LeAnne Zumwalt
Group Vice President
Purchasing and Public Affairs

Flexibility in the Medicare Advantage (MA) Uniformity Requirements

Current Rule/Proposal: Under the current uniformity requirement, MA plans must make benefits available and accessible to each enrollee and establish a uniform premium for each enrollee. CMS has determined that providing access to services tied to health status or a disease state coincides with regulatory and statutory provisions. CMS is 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.

Comment: 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 and welcome the MA VBID demonstration's 2019 expansion to include 15 additional states, Chronic Condition-Special Needs Plans (C-SNPs), and more conditions, such as chronic kidney disease (CKD). To be clear, DaVita does not oppose CMS's proposal to permit targeted supplemental benefits for medically vulnerable beneficiaries. However, implementing a revised uniformity requirement in the upcoming contract year raises important timing and other practical issues that we respectfully urge CMS to consider.

Although CMS's work to design the MA VBID demonstration will inform development of the potential guidance, the demonstration's limited duration and scope to date may not have afforded sufficient time to fully understand the implications of expanding demonstration features on a program-wide basis. It is our understanding that CMS plans to incorporate guidance on a revised uniformity requirement into the 2019 Advance Notice/Call Letter. On previous occasions, CMS has provided more specific information about, and sought feedback on, significant policy changes well in advance of an upcoming year's Advance Notice/Call Letter. Given the condensed comment period and breadth of the Advance Notice/Call Letter, stakeholders may not have a meaningful opportunity to offer informed responses on the guidance. In sum, we are concerned that applying a revised uniformity requirement next year could be considered premature, subjecting it to criticism on process grounds, and as a result, set back efforts to apply VBID principles more broadly under MA over the long term.

To avoid that outcome, if CMS decides to issue the guidance, it could consider a measured approach 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 preamble notes that MA plans must use objective and measurable medical criteria to identify eligible beneficiaries, but it does not indicate the party responsible for establishing the criteria. Initially applying CMS-defined criteria, as done in 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 targeted conditions 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 must comply with clear CMS guidelines on acceptable data sources.

We also urge CMS to consider the interactions between a revised uniformity policy and other proposals, such as allowing variations in benefits by service area segments and eliminating the meaningful difference standard. Although CMS does not expect a significant increase in the number of MA plans due to these policies, 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, CMS must pay close attention to network designs and other plan features to prevent MA organizations from introducing 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 – whether purposeful or not – warrants subjecting provider networks under MA plans offering condition-specific benefits to a higher level of scrutiny on an annual basis. Finally, in keeping with CMS's efforts to promote greater transparency, it could consider conducting and releasing an analysis of condition-specific plans that identifies best practices and allows stakeholders to understand their impact on quality, beneficiary satisfaction, and access to providers.

Segment Benefits Flexibility

Current Rule/Proposal: 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 has proposed a revised interpretation that would allow variation in supplemental benefits, in addition to premiums and cost sharing amounts, by segment.

Comment: 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, 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. The proposed rule also does not 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.

In addition, reports suggest that MA organizations' use of the segmentation policy has increased in recent years. Another dimension of variation, coupled with revising the uniformity requirement, could make it more difficult for beneficiaries to understand their options and make sound coverage decisions. We also are concerned that unless closely monitored, permitting variation in benefits by segment could introduce opportunities for MA organizations to discriminate against beneficiaries with higher than average health care needs. Specifically, the proposed revision could result in "gerrymandering" through segment-level benefit designs that allow MA plans to maximize profitability across a service area by avoiding high-need beneficiaries in a segment. If finalized, CMS should clarify the revised policy's interaction with other current segmentation rules and more important, outline steps it will take to curtail introduction of any discriminatory activities that may result from the policy.

Meaningful Differences in MA Bid Submissions and Bid Review

Current Rule/Proposal: 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. CMS proposes discontinuing the meaningful difference requirement beginning with the 2019 contract year MA bid submissions.

Comment: DaVita appreciates CMS's detailed explanation of the meaningful difference standard and its intention to foster benefit design innovation through its elimination. We understand that other proposals, such as allowing condition-specific benefit designs, could complicate application of the meaningful difference standard. That said, we are not completely confident that its wholesale elimination is prudent. As CMS noted, 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.

Maximum Out-of-Pocket (MOOP) Limit for Medicare Parts A and B Services

Current Rule/Proposal: CMS sets the voluntary and mandatory MOOP limits at approximately the 85th percentile and 95th percentile of projected cost sharing for beneficiaries in Medicare FFS. MA plans that adopt the voluntary lower MOOP limit have greater flexibility in establishing Parts A and B cost sharing for certain benefits. CMS is proposing new regulatory authority to balance limiting MOOP costs and potential changes in premiums, benefits, and cost sharing amounts; allow MOOP limits to be determined using a different methodology; increase the voluntary MOOP limit to another Medicare FFS percentile level; expand the permissible service categories that can have higher cost sharing in exchange for offering a lower MOOP limit; and implement more than two MOOP levels and cost sharing limits to encourage adoption of a lower MOOP limit.

Comment: DaVita strongly supports the voluntary and mandatory MOOP limits, which CMS determined were necessary in order not to discourage MA enrollment by beneficiaries who utilize higher than average levels of health care services. The MOOP limits help beneficiaries estimate their out-of-pocket costs and offer important financial protections from excessively high or unexpected cost sharing. As noted in the proposed rule, maintaining year-to-year stability in MOOP amounts is crucial for both MA organizations and beneficiaries. We encourage CMS to finalize the language that codifies CMS's discretion to balance factors to achieve that objective.

As CMS contemplates other MOOP-related proposals, we urge it to consider another fundamental reason for the development and application of MOOP limits, namely that over time MA plan offerings have become increasingly complex. We appreciate the interest in encouraging adoption of a lower MOOP limit and the relief it can bring to beneficiaries. That said, we are concerned that the potential expansion of service categories to which higher cost sharing can apply and establishment of more than two MOOP and cost sharing levels could undermine the purpose of MOOP limits by making them more complicated.

Cost Sharing Limits for Medicare Parts A and B Services

Current Rule/Proposal: MA plans' cost sharing for Parts A and B services cannot exceed levels determined annually by CMS to comply with non-discrimination rules. In reviewing plans' cost sharing amounts, CMS applies parameters based on Medicare FFS data that reflect a combination of patient utilization scenarios and length of stays or services used by average to sicker patients. Under statute, cost sharing for chemotherapy administration services, renal dialysis services, and skilled nursing care cannot exceed cost sharing for those services under Parts A and B. In general, for other services to be considered non-discriminatory, CMS has established that MA plans must pay at least 50 percent of the contracted (or Medicare allowable) rate and stipulated that cost sharing for services cannot exceed 50 percent of the total MA plan financial liability. CMS has proposed clarifying that it may use Medicare FFS data to establish appropriate cost sharing limits. CMS also is seeking comments on codifying the use of encounter data to inform patient utilization scenarios used to identify cost sharing standards and thresholds that are not discriminatory.

Comment: DaVita appreciates the careful analyses of MA plans' cost sharing levels and certainly agrees that CMS should use the most relevant and appropriate information when determining cost sharing standards. That

said, the validity and reliability of encounter data have been questioned. In fact, as we are sure CMS knows, a January 2017 Government Accountability Office (GAO) reiterates its 2014 recommendation that CMS not move forward in using encounter data for MA payment or other purposes until it validates the data's accuracy and completeness. We understand that in the immediate future, CMS does not expect to incorporate encounter data into its analyses to establish cost sharing limits. Before exercising any authority to do so, CMS should develop and execute plans to confirm that the data meet accuracy and completeness.

Coordination of Enrollment and Disenrollment through MA Organizations

Current Rule/Proposal: CMS is proposing a default enrollment process for Medicaid managed care enrollees newly eligible for Medicare into Dual Eligible-Special Needs Plans (D-SNPs) if plans and states meet certain conditions. In addition, CMS has proposed a simplified election process for current members seeking to convert from non-Medicare coverage to MA coverage offered by the same organization.

Comment: Although DaVita supports adoption of the enrollment processes, we encourage CMS to affirm that the proposals will not inappropriately curtail the election rights of individuals with ESRD. Specifically, the policies' descriptions reference "individuals newly eligible for Medicare," and the scenarios largely focus on individuals who receive Medicare upon attaining age 65. However, as CMS knows well, an important distinction exists between Medicare coverage based on age and an ESRD diagnosis. Rather than automatic enrollment, individuals with ESRD have the option to apply for Medicare, and they are not eligible until they receive a favorable determination on their application.

The proposed rule's broad reference to "individuals newly eligible for Medicare" may cause confusion, leading some plans to equate an ESRD diagnosis – in and of itself – with Medicare eligibility or require an individual with ESRD to apply for Medicare. Unfortunately, DaVita has encountered numerous instances in which plans have informed individuals with ESRD covered under other business lines that they must enroll in Medicare. These actions deny individuals with ESRD their rights to elect coverage that best meets their needs. Many individuals with ESRD are left with Medicare FFS as their only option, which can lead to significant financial exposure. To be clear, we strongly support MA as an option for individuals with ESRD; however, ESRD patients' decisions to elect Medicare should not be dictated by a plan. CMS should establish that it would not tolerate any enrollment policies that run counter to the Medicare eligibility and enrollment rules that afford individuals with ESRD the option to apply for Medicare.

Codification of the MA Star Rating System

Current Rule/Proposal: CMS plans to codify the current MA Star Rating System. The proposal largely retains the current framework with some changes related to star rating determinations upon an MA contract consolidation. CMS also has requested feedback on requiring reporting at the plan level for all plans including D-SNPs and the organization level for certain measures (e.g., call center measures).

Comment: The MA Star Rating System is a powerful tool to improve quality and inform beneficiaries' MA plan election decisions. In general, DaVita agrees that the rating system's maturity makes codification an appropriate action that will afford greater year-to-year stability, predictability, and transparency. We understand the need to include the interim categorical adjustment index (CAI) process in the codification; however, we strongly urge CMS not to diminish its efforts to formulate a more robust approach to account for performance disparities stemming from larger shares of enrollees who receive the low-income subsidy (LIS) and/or are dually eligible (DE) and disabled. As part of the work to improve the CAI and develop a long-term solution, CMS should consider incorporating factors beyond the current LIS, DE, and disabled categories and those recommended by the Assistant Secretary for Planning and Evaluation (ASPE). As currently defined, the social factors may leave out some important categories of beneficiaries, such as those who are homeless, but non-DE

and non-Hispanic, non-DE beneficiaries who may have low incomes and low literacy, but who reside in an area not designated as low income.

DaVita also appreciates CMS's discussion about the advantages and disadvantages of contract– and plan-level reporting. As CMS noted, although contract-level reporting can ensure sample sizes necessary for valid and reliable measurements and minimize reporting burdens, beneficiaries elect a plan, not a contract. Some contracts span multiple states and tens of thousands of beneficiaries, making it challenging – if not impossible – to discern quality at a local level. Plan-level assessments can mitigate, but not eliminate, this issue because they also often have expansive service areas with counties that may not be contiguous. The flexibility proposed in the rule, such as condition-specific benefits, heightens the need to develop other approaches to assess the impact of novel benefit designs' effect on quality, outcomes, and beneficiary satisfaction at a more granular level. We urge CMS to continue its work on this issue and consider ideas, such as MedPAC's recommendation to examine quality based on the organization of local health care markets.

Limitations on Tiering Exceptions

Current Rule/Proposal: Part D sponsors using tiered formularies must have a process through which an enrollee can request an exception to the cost sharing structure, such as obtaining a drug on a higher cost sharing tier at more favorable cost sharing applicable to other drugs on a lower cost sharing tier. Part D sponsors do not have to apply an exceptions process to "generic" tiers. CMS has proposed revisions to prevent MA organizations from inappropriately avoiding the application of an exceptions process to a tier labeled "generic."

Comment: As CMS noted, formulary designs have changed significantly since the Part D program's inception with many Prescription Drug Plans (PDPs) now using formularies with five or six tiers. The availability of an exceptions process is crucial to ensuring the affordability of, and preserving beneficiaries' access to, prescription medicines recommended by their providers. DaVita supports CMS's proposal to require that Part D sponsors continue to meet the statute's and regulation's spirit and intent regarding the availability of tiering exceptions.

Communications/Marketing Materials

Current Rule/Proposal: Current rules require MA organizations and Part D sponsors to submit marketing materials and application forms 45 days prior to their use. Marketing materials are broadly defined as those that: promote the organization; inform beneficiaries that they may enroll or remain enrolled; explain the benefits of enrollment or rules; and explain how benefits are covered. Rules establish examples of marketing materials, which include, but are not limited to, brochures, telemarketing scripts, slide presentations, and member communications. CMS has proposed creating a distinct communications materials category, of which marketing materials would be a subset.

Comment: DaVita shares CMS's concern that the current regulatory framework may be overly broad, necessitating review and approval of materials not intended to inform or influence a beneficiary's enrollment decision. Although establishing the two categories appears to be a reasonable approach, we respectfully disagree with CMS's view that beneficiaries do not rely on materials, such as the Evidence of Coverage (EOC), in making enrollment decisions. As CMS noted, some materials include more detailed information about the MA plan's design and rules. Understanding how plan designs and rules affect access to providers or services is particularly important for beneficiaries with a chronic illness. The introduction of more complex benefit designs, as envisioned by the proposed rule, makes it more imperative that beneficiaries have access to materials that clearly explain plan requirements. We appreciate that if CMS finalizes the proposed policy, it will continue to scrutinize communications materials prior to their use and require marketing materials to include adequate descriptions of plan rules and procedures. To ensure that beneficiaries can make informed coverage decisions, CMS must continue to set a high bar when reviewing these materials.

In addition, as CMS contemplates changes to its MA plan communications and marketing oversight activities, we urge it to consider the unique challenges that some beneficiaries face when making coverage decisions and the role providers can play to help them understand their options. For example, beneficiaries with ESRD spend 12 to 15 hours each week at a dialysis facility with their physicians and dialysis center staff. Although information can be distributed before or after dialysis treatment sessions, it can be difficult for patients to set aside the additional time necessary to learn more about their coverage options. The treatment area is an ideal location for clinical and non-clinical staff to help beneficiaries with ESRD assess their coverage choices; however, MA marketing guidelines prohibit this activity. To be clear, we appreciate and respect the need to ensure that beneficiaries make independent coverage decisions. Given the depth of their patient-provider relationships, we urge CMS to consider permitting physicians and dialysis center staff to distribute on the dialysis treatment floor plan materials aimed at helping beneficiaries assess MA coverage options relative to their treatment plans, goals, and preferences. Permitting providers who are intimately familiar with patients' treatment plans to undertake these activities – with appropriate safeguards to ensure beneficiaries' independent coverage choices – can be particularly helpful as beneficiaries work to evaluate MA plans offering condition-specific benefits.