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

Re: File Code CMS-5527-P; Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures; Proposed Rule

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our comments to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed Radiation Oncology Model (RO Model) and the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model). The AMA strongly supports the development of better payment models for radiation oncology and for care of end-stage renal disease patients. We recommend a number of changes in the proposed models to help them better achieve our shared goals of improving patient health outcomes while avoiding unintended consequences for patients and physicians. Our recommendations to improve the proposed models are summarized below.

**RO Model Recommendations**

- **The AMA supports the creation of a bundled episode payment model for radiation oncology.** An appropriately-designed RO Model could enable physicians to deliver higher quality care at lower cost, and we have supported and encouraged efforts to develop such an APM for several years.

- **The proposed RO Model would address several important problems with the current payment system for radiation oncology.** The proposed RO Model would give physicians greater flexibility to deliver services and enable them to deliver lower-cost treatments without being financially penalized.

- **Modifications should be made to the proposed RO Model:**
  - Stratify the bundled payments based on the clinical characteristics of patients that significantly affect the number and type of treatments they will receive.
  - Modify the proposed efficiency and quality adjustments to avoid penalizing physician practices whose patients have greater needs.
  - Adjust payments to account for the higher costs of delivering services in rural communities.

    - Base payment amounts on the cost of delivering services and make initial payment amounts budget-neutral.
    - Adjust payment amounts annually for changes in evidence, technology, and inflation.
    - Pay for data collection to support development of outcome measures.
    - Hold patients harmless from increases in cost-sharing.

- **A limited scale test of a revised radiation oncology alternative payment model (APM) should be conducted on a voluntary basis rather than mandating participation in an untested model.** Even with improvements, a RO Model represents major changes in payment for services that treat life-threatening illnesses. It is inappropriate to mandate participation in a payment model involving such sweeping change without any testing on a more limited scale with practices who voluntarily participate.

**ETC Model Recommendations**

- **We support the creation of a Home Dialysis Payment Adjustment (HDPA) to enable increased use of home dialysis for appropriate ESRD patients.**

- **We recommend that the amount of the proposed HDPA be increased significantly and continued for the life of the demonstration.** As proposed, the payment amount is too small for the HDPA to effectively address current gaps in payments for home vs. center dialysis, and it is inappropriate to phase it out in three years.

- **The Performance Payment Adjustment should be eliminated.** Eligible nephrologists already participate in the Merit-based Incentive Payment System (MIPS), which provides positive or negative payment adjustments based on performance. Unless the ETC Model is redesigned to qualify as an Advanced APM, it would not exempt physicians from MIPS. Thus, physicians would be required to participate in two simultaneous and uncoordinated pay-for-performance programs, which would increase physician reporting burdens in a way that is clearly at odds with the CMS Patients Over Paperwork initiative.

- **The Home Dialysis Rate and Transplant Rate measures should be significantly revised before they are used to modify physician payments in any way:**
    - A performance measure for the use of home dialysis should focus on those patients who can feasibly and safely utilize home dialysis.
    - A performance measure for transplants should focus on the proportion of patients who are on transplant waiting lists, not the proportion who receive transplants.

The remainder of this letter provides a more detailed explanation of our recommendations and the issues in the proposed models that they are intended to address.

**RO Model Payment Goals**

Radiation therapy treatments for patients with cancer require the use of expensive facilities and equipment. Because the cost of the facilities and equipment is fixed at any point in time, the average cost of treatment per patient is higher when fewer treatments are delivered. This means that treatment facilities are financially penalized when they use more conservative treatment plans involving fewer treatments or lower-cost treatment modalities. Moreover, treatment facilities in many rural areas incur higher costs per

patient simply because there are fewer patients who need particular kinds of treatment than the maximum number of patients who could be treated using a single piece of equipment.

Even if they do not own and operate expensive treatment equipment, radiation oncologists experience similar problems. While practice costs are fixed, radiation oncologists are paid based on the number of services they deliver, so delivering fewer services or practicing in rural areas can lead to financial losses. Current payment systems create an additional problem for physician practices, though, as oncologists are not paid at all for some services that improve cancer care, such as care management, and in other cases, payments may be inadequate to support the time needed to deliver high-value care. To address these issues, the bundled episode payments for radiation oncology should:

- provide flexibility to deliver the most appropriate type and number of services to patients based on the type of cancer and other relevant clinical characteristics of the patient;
- avoid penalizing practices or facilities financially for using fewer or lower-cost treatments when appropriate, and avoid rewarding them for using more treatments or more expensive treatments than are necessary or appropriate based on evidence;
- be based on the expected cost of the types of treatment that evidence indicates are appropriate for patients with particular types of cancer and other characteristics;
- reflect differences in costs that facilities would expect to incur to deliver evidence-based treatment in communities with small numbers of potential patients, such as rural areas;
- give physicians the flexibility to manage patients' care in different ways, such as phone and email contacts with patients not just face-to-face visits; and
- support the time radiation oncologists need to determine the most appropriate treatments based on current evidence, engage in shared decision-making processes with patients about treatment plans, and provide care management services to help patients avoid and address complications of treatment and overcome barriers to achieving good outcomes.

**Analysis of Proposed RO Model Payments**

The proposed model would replace RO payments under the Medicare Physician Fee Schedule (MPFS) and Outpatient Prospective Payment System (OPPS) with two bundled payments:

- A single bundled "Technical Component (TC)" payment for all of the treatments delivered at a treatment facility during a 90-day episode of care for an individual patient.
- A single bundled "Professional Component (PC)" payment for all of the treatment planning and management services delivered by a physician practice to the patient during the same 90-day episode of care.

This bundled episode payment approach has the potential to address several important goals that are outlined above:

- physicians and facilities would have the flexibility to deliver lower-cost treatments and fewer treatments without being financially penalized for doing so;
- physicians and facilities would not be financially rewarded for using more treatments or more expensive treatments that are not based on evidence; and
- physicians would have flexibility to deliver services that are not currently billable under the MPFS.

However, the proposed model design does not address several other important goals. It could also exacerbate some of the problems with the current payment system. For example, the proposed methodology for setting payment amounts does not include any mechanism for ensuring that the amount

of the bundled episode payment will be adequate to cover the cost of the types and amounts of treatment that evidence indicates are appropriate for patients with particular types of cancer and other characteristics. Several modifications should be made to improve the way payment amounts are established under the model.

- **Bundled payments should be stratified based on clinical characteristics of patients.** As proposed, payments would be based on average spending in the past for all patients with a particular type of cancer, even though there are significant differences in the types and amounts of treatments that are appropriate for patients with different stages of the same type of cancer and other differences in patient characteristics (84 FR 34505-34506). Although the regulation indicates that payment amounts will be adjusted for case mix, it does not adequately define the case mix adjustment and the information that is provided is problematic. Case mix adjustment should *not* be based on “beneficiary characteristics found to be strongly correlated to cost” as the regulation states; case mix adjustment should be based on beneficiary characteristics *that affect the appropriate type and amount of evidence-based treatment* (84 FR 34504). Unless payments are adjusted for these characteristics, patients who are referred to a physician practice or treatment facility with characteristics that require more expensive treatments will cause the practice or facility to suffer financial losses from inadequate payment. Many of the most important patient characteristics that determine what treatment is appropriate will be reflected in clinical data, not claims data, so it will be impossible for CMS to define an adequate case mix adjustment simply by running a regression on information contained in claims data such as age, sex, diagnosis, and other procedures or treatments (84 FR 34507).

  Instead, the bundled payments should be stratified based on the clinical characteristics of patients that significantly affect the number and type of treatments they will receive, not just the broad category of cancer they have. This will allow payments to match the needs of the patients and the costs of appropriate treatment as closely as possible. This stratification should be developed in collaboration with radiation oncologists. The radiation oncologist who plans the patient’s treatment should be given the ability to determine which payment category is appropriate for an individual patient and to document the basis for the assignment. This will result in more accurate classifications than CMS could make using claims data, and it will also avoid the need to require physicians to submit large amounts of clinical data that may never be used.

- **Payment amounts should be adjusted annually for changes in evidence and technology.** It is well known that new treatments for cancer are being developed at a rapid pace and new evidence regarding the relative effectiveness of different treatments is appearing almost daily. Despite these rapid changes, the proposed methodology bases both payment amounts and case mix adjustments on the treatments that were used in the past, with no adjustment for changes in technology or evidence (84 FR 34503 and 84 FR 34505). The regulation proposes to “trend” the payment amounts based on changes in Medicare payments under the MPFS and OPPS and changes in utilization by providers who are not participating in the RO Model, instead of changes in the costs of technologies used for treatment and the mix of treatments that evidence indicates are appropriate (84 FR 34503 and 84 FR 34507). The regulation also explicitly indicates that the coefficients of the case mix adjustment formula would not change from year to year, even though it is highly likely that changes in technology and evidence will change the types of treatments that are appropriate for different patients as often as annually (84 FR 34507). CMS should work with radiation oncologists to adjust payment amounts each year to incorporate revised approaches to

care delivery, new evidence about treatment effectiveness, changes in equipment costs, and availability of new technologies.

- **Payment amounts should be based on the actual cost of delivering evidence-based services and initial payment amounts should be budget neutral.** A fundamental principle behind all Medicare payment systems is that payments should be based on the actual cost of delivering services. Yet rather than determining what it does cost or should cost to treat patients with a particular type of cancer, the proposed methodology would simply apply an arbitrary discount to the average amount that Medicare is currently spending on those patients. There is no information provided in the proposed regulation to support a 4 percent "discount" for professional services or a 5 percent "discount" for treatment services. Instead of these discounts, the amounts of the initial bundled payments for each participating practice should be based on the average amounts they spent during the previous year on patients in each clinical category plus adjustments based on any changes in evidence or technology that are expected to influence treatment during the coming year. CMS should not impose a "discount" unless there is an analysis clearly showing that efficiencies of at least that level can be achieved using the flexibility and predictability of the bundled payment.

  In addition, payment amounts for treatment should not be based only on spending for services delivered in hospital outpatient departments, as this will exacerbate payment inaccuracies. The regulation inappropriately claims that payments under the OPPS are "based on a stronger empirical foundation" than payments under the MPFS, even though in other areas, CMS has proposed site-neutral payments based on MPFS amounts rather than OPPS amounts (84 FR 34505). Payments under the OPPS rely on hospital charges to apportion costs to individual services, even though it is widely known that the amount a hospital charges for a service does not have any direct or consistent relationship to what the service actually costs. In contrast, payment amounts under the MPFS are based on an estimate of the time and costs associated with that specific service.

  It appears that CMS is favoring OPPS rates in this instance because it believes that utilization of services is higher for patients treated in stand-alone facilities than in hospital outpatient departments (HOPDs). The proposed rule cites a CMS analysis showing that radiation therapy episodes delivered in freestanding treatment centers were paid 11 percent more than episodes delivered in HOPDs and that CMS is not aware of any clinical rationale that explains these differences. Yet the only patient characteristics used to try and explain the differences were those "available in claims" (84 FR 34490). The "RO Episode File (2015-2017)" released along with the regulation does not provide sufficient information about the patients to determine whether the patients were overtreated in freestanding facilities or undertreated in HOPDs, or whether there were clinical differences in the types of patients treated in the two settings that justified the differences.

- **Proposed "efficiency" adjustments should be modified to avoid penalizing physician practices and treatment centers who treat patients with greater needs.** In the proposed payment methodology, CMS would calculate whether an individual practice had higher or lower spending than the CMS case mix adjustment would predict, and then apply an "efficiency factor" to reduce the difference. Although well-intended, this component of the methodology magnifies the errors that will result from using the problematic case mix adjustment methodology. If a practice has patients who require more or higher cost treatments, but the difference is not

captured adequately by the case mix adjustment, the practice will appear "inefficient" even though it may actually be using the most conservative method of treating the patients. The proposed "efficiency factor" will then adjust the practice's payments by only 70-90 percent of the actual difference in payment it needs to support those services (84 FR 34504 and 84 FR 34508). This will financially penalize practices that appropriately treat patients who require more expensive or frequent treatments.

- **The quality component of the proposed model should be modified to reward high quality care.** In contrast to MIPS, where physicians can receive higher payments for high performance on quality measures as well as reduced payments for low performance, the proposed quality component in the RO Model involves only penalties. Every participant would have their payments reduced by 2 percent under the proposed "quality withhold," and then a portion of that withhold would be returned based on the practice's "Aggregate Quality Score (AQS)." This means that at best, a very high performing practice might receive no payment reduction for quality, but they would have to wait over a year to receive the 2 percent withhold back. Most practices would only have a portion of the 2 percent withhold returned, which would represent a net pay cut (84 FR 34509).

  The effects of this cut will be even greater on high-performing practices because CMS proposes to eliminate MIPS payment adjustments for physicians who do not meet the criteria for a Qualifying APM Participant (QP). This would result in an additional payment reduction for those practices that would have received a bonus under MIPS in the absence of the RO Model. For physicians who do qualify as QPs, CMS proposes to exclude the technical component of the payments from the 5 percent MACRA APM incentive payment that would have otherwise offset a portion of the losses under the proposed model (84 FR 34525). Physician practices should receive the incentive payment enacted by Congress on all of their revenues.

- **Payment amounts should be adjusted for the higher costs of delivering services in rural communities.** The proposed methodology does not include any mechanism for adjusting payment amounts to reflect the higher cost of an episode of care in rural communities. The geographic adjustment may address some of the differences in the higher cost-of-living between different communities, but it does not compensate for the higher average cost per patient in facilities and practices that treat smaller numbers of patients. In its November 2017 *Report to Congress: Episodic Alternative Payment for Radiation Therapy Services*, CMS reported that this issue was specifically raised in its public listening session on May 3, 2017, but there is no information in the proposed regulation indicating that CMS has examined this issue.

  In combination, the proposed discounts and quality/patient experience adjustments could result in at least a 4-5 percent cut in payments and as much as a 6 percent cut for both radiation oncology practices and treatment facilities. The "efficiency adjustment" could result in an additional cut of several percentage points for practices whose patients need more-expensive-than-average treatments. The "incorrect payment withholds" will delay an additional 2 percent of payments by as much as 21 months. This means that radiation oncology practices could initially experience revenue reductions of 8 percent or more under the proposed model. This could force some practices to close, particularly in rural areas, and independent practices could be forced to merge with hospitals and health systems to cover their costs.

- **The RO Model should provide payments for data reporting and support development of outcome measures.** CMS proposes to require participants to report an unspecified amount of clinical information on patients to CMS, respond to requests for information from evaluators, and implement peer reviews and other new procedures. As proposed, this data collection and reporting would be uncompensated and could reduce productivity. Since there are currently no outcome measures available for radiation oncology, the RO Model should be used as an opportunity to create such measures. Similar to what has been done in the Comprehensive Care for Joint Replacement Model, radiation oncology practices should receive higher payments if they collect and submit data on patient outcomes that can enable the development of new measures.

- **Patient cost-sharing should be modified.** CMS proposes that patients treated by RO Model participants would pay 20 percent of the bundled payment amount that the practice or facility receives, rather than 20 percent of the amounts that Medicare would have paid under the MPFS and/or OPPS for the specific services that the patient received. This means that patients who receive fewer or lower-cost services than average for their type of cancer would pay more in cost-sharing than if they had received the same treatment in a non-participating region, whereas patients who receive more services than average would pay less in cost-sharing. Although CMS indicates that it believes cost-sharing will be "lower on average," and although many patients have supplemental insurance that will shield them from higher cost-sharing amounts, some patients may be harmed financially by this approach (84 FR 34510).

  In addition, it is possible that some patients who live in the outer areas of a participating CBSA that is adjacent to a non-participating CBSA, or who otherwise could easily access treatment facilities in both participating and non-participating regions, could decide to change the location of their treatment based on the difference in cost-sharing under the proposed RO Model or concerns about the potential for undertreatment in response to payment cuts. This would increase costs for Medicare, cause financial losses for providers in participating regions, and bias the evaluation results. Instead, CMS should base patient cost-sharing on the lesser of (a) what the patient would have paid in cost-sharing under standard Medicare payment amounts for the specific services the patient received, and (b) 20 percent of the bundled payment amount. This will remove any disincentive for a patient to obtain treatment from a participating practice and enable patients to share in the savings from using a bundled payment.

**The RO Model Should Be Voluntary**

The proposed RO Model represents a major change in payment for services that treat life-threatening illnesses, and the many issues described above threaten its ability to succeed. Although a number of the concerns could be addressed through the improvements we have recommended, the AMA believes that "field testing" a preliminary version of the model with voluntary participants is the best way to structure the model. As a direct corollary of this, it is inappropriate to mandate implementation of the proposed model or even a revised version of the model in 40 percent of the nation before such field testing occurs. The risk of creating significant harm to seriously ill patients is simply too great. In addition, CMS is proposing so many changes in payment simultaneously (a bundled payment, a site-neutral payment, a new method of determining payment amounts, and a large "discount" compared to current payments) that an evaluation will not be able to separate the impacts of each change using the proposed randomization process.

We believe that there are many physician practices and treatment facilities that will be willing to pilot test a well-designed payment model that has the potential to improve the quality and affordability of care. In fact, bundled episode payment models in radiation oncology have been in use in the private sector for several years, and the radiation oncology specialty societies have developed proposals for such models. A voluntary pilot test would provide the critical information (a) that CMS needs to refine the model for broader implementation, and (b) that CMS could not obtain in any other way. Multiple voluntary pilot tests on a smaller scale would allow different versions of the model to be tested in order to determine which payment approach would have the greatest impact with the fewest unintended consequences. CMS has used multiple "tracks" in other model tests to do this and a similar approach would be desirable here.

If CMS feels that a large-scale test is needed to evaluate the impacts of the model, CMS could implement the model on a voluntary basis in randomly selected regions. However, if there is widespread agreement that the model is desirable, it would be preferable to implement the model on a voluntary basis nationally, similar to the approach used in the Medicare Shared Savings Program, and evaluate its impact using an interrupted time series approach rather than a control group. That would enable all Medicare patients to receive the benefits of better care and deliver more savings to Medicare more quickly.

**Recommended Approach to Refining and Testing an APM for Radiation Oncology**

In order to address the concerns described above, we recommend the following approach:

- **Release detailed data and analyses on radiation oncology spending before attempting to finalize the design of a model.** To date, CMS has not released detailed information on variation in radiation oncology spending that could enable radiation oncologists to determine the extent to which unwarranted variation in spending exists and to analyze the impacts of the proposed payment model. Releasing such information would be a better way to "offer participants the opportunity to examine and better understand their own care processes and patterns" than immediately mandating participation in an untested payment model. Moreover, access to these data would help radiation oncologists recommend refinements to the payment model and also help them prepare to participate.

- **Conduct a limited scale test of two or more versions of a radiation oncology APM on a voluntary basis.** The AMA urges CMS to conduct limited scale testing with interested practices before pursuing broader testing or implementation on the scale envisioned in the proposed regulation. In addition, CMS could invite the radiation oncology community to develop one or more proposals for APMs and test at least one of these proposals in addition to a modified version of the proposed RO Model before determining which approach to use in a broader scale test.

**Analysis of Proposed ESRD Treatment Choices Model**

**Home Dialysis Payment Adjustment (HDPA)**

We commend CMS for seeking ways to encourage greater use of home dialysis. As documented in the proposed rule, home dialysis can provide better outcomes and greater convenience for many beneficiaries at a lower cost to the Medicare program. We believe that improving the way nephrologists are paid for home dialysis is essential to encourage and facilitate greater use of home dialysis because of the significant barriers created by the current payment rules. As is documented in the proposed regulation (84 CFR 34537), the requirement for at least one in-person visit per month creates unnecessary problems for

both the nephrologist and the patient; although the requirement can be waived, this requires documentation that services are being provided and a review by the Medicare Administrative Contractor. In addition, Medicare pays a nephrologist 19 percent more ($47 per month) for a patient receiving in-center dialysis than for a patient receiving home dialysis. Although more visits per month are required for a patient receiving in-center dialysis, it is more efficient for a physician to see patients in a dialysis center than in the office, and it is even more expensive for a physician to visit with a patient at home. As noted in the proposed regulation, the May 2015 GAO report on home dialysis describes this problem as one of the key barriers to increasing the use of home dialysis (84 FR 34541). In addition, the GAO report notes that dialysis facilities incur higher costs for home dialysis than for center dialysis.

Increasing payments for home dialysis through an HDPA could help to overcome these barriers, but modifications are needed to the proposed HDPA in order for it to be successful:

- **Increase the size of the Home Dialysis Payment Adjustment.** Physicians understand the benefits of home dialysis and would like to see as many of their patients as possible utilizing it, but under the current payment system, they are financially penalized when more of their patients are on home dialysis. Physicians do not need an "incentive" to use more home dialysis, they need Medicare payments that are adequate. The proposed HDPA amounts are insufficient to address the current gaps in physician payments.

  For nephrologists, the proposed 3 percent HDPA in CY2020 would represent only $7.27 per patient per month more than what the physician would otherwise be paid for home dialysis patients age 20 years and older, and the 1 percent HDPA in CY2022 would represent only $2.42 per patient per month (84 FR 34547). These amounts would reduce the current payment gap for home dialysis patients by only 5-15 percent, and only for a period of 3 years.

  The regulation provides no justification for choosing 1 percent to 3 percent as the amounts of the HDPA and no evidence that those amounts would address the current barriers to home dialysis described in the regulation. Moreover, the HDPA is inappropriately described as a "process-based incentive approach." As documented in the regulation, a clear connection exists between the "process" of home dialysis and better outcomes for appropriate patients.

  We recommend that the HDPA amount be based on an analysis of the costs of supporting home dialysis.

- **Continue the Home Dialysis Payment Adjustment for the life of the demonstration.** The regulation justifies phasing out the HDPA after only 3 years by suggesting that the proposed Performance Payment Adjustment (PPA) would replace the HDPA, but as discussed below, we believe that the PPA should be eliminated. Even under the proposed PPA, most physicians would likely receive no change in their payments under the PPA if they successfully increase the proportion of patients receiving home dialysis because of the way the scoring methodology is defined. Since the regulation does not make any changes in the underlying payment system for dialysis, **the barriers to home dialysis in the current payment system will continue to exist after the HDPA ends**. New patients will develop ESRD every year, and they should have the same opportunity to receive dialysis at home regardless of when they begin dialysis. For the same reasons, it is inappropriate to reduce the HDPA after only 1 year.

We recommend that the HDPA be paid for more than 3 years, with no reduction in amount, and with increases to reflect inflation in costs during the life of the program.

**Performance Payment Adjustment**

Instead of creating an APM to support more home dialysis and transplants, CMS proposes a "pay-for-performance" (P4P) system that imposes penalties on dialysis providers and pays bonuses to them without any modifications to the existing dialysis payment systems that would enable them to improve their performance.

Nephrologists already participate in the MIPS program, which provides penalties and bonuses based, in part, on their performance on quality measures. The proposed PPA is "designed to be comparable to the MIPS payment adjustment factors for MIPS eligible clinicians." Yet participation in the ETC Model would not exempt the physicians from MIPS, so they would be required to participate in two simultaneous, uncoordinated performance-based payment programs, creating unnecessary burdens and complexity. If CMS wants to reward or penalize physicians based on efforts to encourage home dialysis and transplants, the AMA urges that CMS include appropriate measures in the MIPS program, rather than creating an additional P4P program.

We also do not understand the rationale for creating the ETC Model when CMS has announced plans to implement Kidney Care First (KCF) and Comprehensive Kidney Care Contracting (CKCC) APMs that could facilitate greater use of home dialysis and kidney transplants in a more effective way. Although the regulation indicates that the proposed ETC Model would be "complementary" to the KCF and CKCC APMs, the disparate structures of the programs would be problematic for physicians and patients and would cause problems for the evaluation of all of the programs. For example, the ETC Model would be mandatory for some providers who will be unable to participate in KCF or CKCC, while the ETC model would not be used for KCF and CKCC participants in regions that are not selected for the ETC model.

**We urge that the PPA be eliminated.** The MIPS program should be used to make performance-based adjustments to MPFS payments. True APMs should be created to provide nephrologists with the opportunity to obtain the resources and flexibility they need to improve outcomes and reduce spending for ESRD patients.

**Home Dialysis Rate and Transplant Rate Measures**

Before the Home Dialysis Rate and Transplant Rate measures are used to modify physician payments, the following changes should be made:

- **A measure of the use of home dialysis should allow physicians to exclude ineligible patients from the denominator.** The proposed denominator for the proposed Home Dialysis Rate measure inappropriately includes all patients receiving dialysis, rather than the subset of patients who could potentially use home dialysis (84 FR 34551). Home dialysis is not an option for many patients, particularly patients who live alone or who do not have a caregiver willing and able to assist them.

- **A measure of the use of home dialysis should be risk adjusted based on characteristics of patients that affect their ability to use home dialysis.** The proposed risk adjustment methodology using HCC scores fails to adjust for differences in the ability of patients to use

home dialysis, which means that nephrologists and dialysis centers will be rewarded or penalized based on the types of ESRD patients they serve, not based on their willingness or ability to encourage eligible patients to use home dialysis. CMS should release the analysis that shows the use of HCC scores is a "sufficient" method of risk adjustment (84 FR 34554).

- **A measure of the use of home dialysis should use a scoring methodology that rewards physicians who increase home dialysis rates.** Under the scoring method proposed in the regulation, physicians who are able to increase the number of patients receiving home dialysis would be unlikely to receive any additional compensation under the proposed scoring methodology (84 FR 34557-34558).
  - A physician practice that increased the proportion of patients receiving home dialysis by more than 5 percent would not qualify for a bonus unless they were at or above the 90th percentile in terms of transplant rates or home dialysis rates.
  - Even a practice that increased the proportion of patients receiving home dialysis by more than 10 percent would not qualify for a bonus unless they were also at or above the 90th percentile on home dialysis rates or above the median in transplant rates.

- **Benchmarks for a measure of home dialysis use should be based on what is known to be achievable.** It is inappropriate for CMS to suggest that it would impose arbitrary standards of performance (such as an 80 percent home dialysis rate after 9 or 10 years) without evidence that such standards can be achieved (84 FR 34556).

- **A measure related to transplants should focus on whether patients are on a transplant waiting list, not whether patients receive a transplant.** The proposed rule explicitly acknowledges that the primary barriers to more transplants are outside the control of physicians. However, the proposed Transplant Rate measure rewards or penalizes physicians based on the proportion of their patients who receive a transplant rather than the proportion of patients who go on the transplant waiting list (84 FR 34552). According to CMS, the "main barrier to kidney transplant is the supply of available organs" and the "transplant incentive would likely increase the share of ESRD beneficiaries who join the transplant wait list but is unlikely to impact the donation supply limitation." Moreover, the impact analysis in the regulation assumes that the number of kidney transplants will not increase (84 FR 34538 and 84 FR 34573-34574). Accordingly, CMS should not reward or penalize physicians based on an outcome that they cannot control or even significantly influence.

- **A measure related to transplants should allow physicians to exclude patients who are not good candidates for transplants from the denominator of the measure.** Failure to do this will cause the rate to appear lower for a group of patients who are less likely to be eligible for a transplant. The proposed approach for risk-adjusting the rate would use age as the basis for adjustment, which is inadequate to address the many factors that can affect a patient's ability to obtain a transplant (84 FR 34555).

- **The denominator of a measure related to transplants should include patients who have received a transplant, not just those who are on dialysis.** Restricting the denominator to the number of patients receiving dialysis will inappropriately cause the measure to vary based on *when* patients receive transplants, not just *whether* they receive transplants. In addition, failure to adjust for preemptive transplants in patients under age 65 would mean that the measure could

unfairly penalize physicians who have a younger mix of patients and who are successful in facilitating preemptive transplants for them.

- **Information on performance should be provided more frequently than annually.** Providing physicians with attribution reports only once per year is insufficient; this will make it impossible for the physicians to determine how they are performing and to take corrective action if needed.

**Recommended Approach to Refining and Testing an APM to Encourage Home Dialysis and Transplants**

To design a successful APM that will encourage greater use of home dialysis and/or transplants, we recommend the following approach:

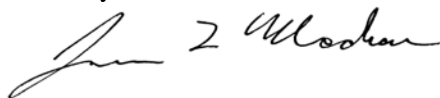
- **Release detailed data and analyses on rates of home dialysis and transplant rates before attempting to finalize the design of a payment model.** Detailed information on variation in home dialysis and transplant rates could enable nephrologists to identify opportunities for increasing the use of home dialysis and transplants. Moreover, access to these data would help physicians to recommend refinements to current payments that would be effective in overcoming the barriers that exist in the current payment system.

- **Conduct a limited scale test of one or more versions of an APM on a voluntary basis.** If CMS thinks that the proposed Kidney Care First and Comprehensive Kidney Care Contracting APMs would not adequately encourage more home dialysis or transplants, we recommend modifying them, or adding additional voluntary tracks, rather than mandating participation in an untested payment model.

**Conclusion**

The AMA appreciates the opportunity to provide our comments and thanks CMS for considering our views. If you should have any questions regarding this letter, please feel free to contact Sandy Marks, Assistant Director of Federal Affairs, at sandy.marks@ama-assn.org or 202-789-4585.

Sincerely,



James L. Madara, MD