American Society of Nephrology

September 16, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445–G
Washington, DC 20201

Re: **CMS-5527-P**: **Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures; The End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model)**

Dear Administrator Verma:

On behalf of American Society of Nephrology (ASN), thank you for the opportunity to provide comments on the proposed rule for the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model developed at the direction of the July 10, 2019, Executive Order on the Advancing American Kidney Health (AAKH) initiative.

ASN's more than 20,000 members are leading the fight to prevent, treat, and cure kidney disease and advocating for the highest quality care for the 37,000,000 Americans and more than 850,000,000 people worldwide affected by kidney disease. In keeping with ASN's mission, we applaud the Trump Administration for creating an ambitious agenda for kidney health. The AAKH initiative promises to bring sweeping changes to care for people with kidney disease, including more focus on upstream treatment to slow the progression of kidney disease, broader choices for dialysis modalities, greater access to transplantation, and concerted support for development of innovative therapies (such as artificial kidneys). ASN strongly supports all these goals and stands ready to work in collaboration with the administration, Congress, and other stakeholders to achieve success.

A critical component of the AAKH Executive Order is the creation of payment models, and these comments apply directly to the proposed rule for the mandatory ETC Model resulting from Section 5 of the Executive Order. Other providers of kidney care may have many similar, parallel suggestions for improvements regarding the proposed model. However, as managing clinicians, our comments primarily reflect the perspective of the nephrology clinician with a focus on the clinician-patient relationship. Our

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comments ultimately will need to be considered within the context of the other four AAKH payment models, the details of which are not yet available.

Essentials for Ensuring Success

We support the objectives of the proposed ETC model to expand patient access to a variety of dialysis modalities and to kidney transplantation. However, we have identified several key essential elements that we believe must be addressed to maximize the likelihood of optimal outcomes for patients and ensure the success of the model. In that spirit, we offer the following recommendations:

- Establishing Appropriate, yet still Audacious, Targets and Benchmarks with a Combined Home Dialysis and Transplant Rate of 50 percent at the Conclusion of the Demonstration Project that is Approached Incrementally
- Empowering Patients and Care Teams to Evaluate the Range of Treatment Options Using Shared Decision-Making Tools and Incorporating Additional Risk Adjustment to Mitigate the Risk of Non-Patient Centered Decision Making
- Guaranteeing Access to Quality Home Dialysis Programs by Aggregating at a Geographic Level Such as a Hospital Referral Region (HRR)
- Incentivizing and Investing Wisely to Ensure Needed Practice Transformation
  a. Reducing the Performance Payment Adjustment (PPA) to a Level Comparable with the ESRD Quality Incentive Program (QIP)
  b. Investing in the Home Dialysis Payment Adjustment (HDPA) at 3-5 Percent Annually for the Life of the Model
  c. Making the Model an Advanced Alternative Payment Model (AAPM)
- Increasing Access to Transplantation by Incorporating Adjusted Transplantation Rates as an Outcome
- Delaying the Start Date of the ETC Model until April 2020, and Implementation of Downside Adjustments Until Measurement Year (MY) Three
- Providing Opportunity for a Second Round of Iterative Comments
- Using the Rulemaking Process for the Model Annually

1) Establishing Appropriate Targets and Benchmarks

Some stakeholders have raised multiple concerns about the proposed ETC model that ASN believes can be appropriately addressed by establishing appropriate targets and benchmarks. Throughout the comment period, ASN has heard from its members and other kidney community organizations that critical guardrails for patients need to be strengthened in the model. As we emphasize throughout these comments, the optimal kidney replacement therapy differs from patient to patient.

Establishing appropriate thresholds and benchmarks provides those important guardrails for patients with contraindications – absolute or relative – or insurmountable barriers for home dialysis or transplant. In addition, correctly risk adjusting the patient population that is to be placed in the denominator for evaluating ETC Participants – clinicians and dialysis facilities – would empower them to make truly shared, patient-

centered choices. Our suggestions throughout this letter reflect our unequivocal belief that those choices need to be patient-centered choices.

We applaud the administration for setting an ambitious goal for increasing transplant and home dialysis rates, which sends an unequivocal message that patients deserve more treatment options than the current system offers. However, we recommend lowering the target goal of 80 percent combined home dialysis and transplant rate in the final years of the ETC model to 50 percent – a still audacious, but achievable, target.

On a philosophical level, we applaud the administration's decision to select such an ambitious goal for new patients with kidney failure starting with home dialysis or transplantation, and we appreciate that it sends a powerful message that the current system of paying for and treating kidney failure care is no longer acceptable. However, from a practical standpoint, achieving this metric in a five-year timeframe is very unlikely. Significant, even seismic, positive change for patients with kidney failure can – and we believe will – occur within five years with the 50 percent target ASN recommends.

As the proposed rule states:

> *At the end of 2016, 63.1 percent of all prevalent ESRD patients – meaning patients already diagnosed with ESRD – in the U.S. were receiving HD, 7.0 percent were being treated with peritoneal dialysis (PD), and 29.6 percent had a functioning kidney transplant. Among HD cases, 98.0 percent used in-center HD, and 2.0 percent used home hemodialysis (HHD).*

ASN believes – with significant effort – patients and nephrology health professionals can increase home dialysis from approximately 12 percent to 25 percent of new patients starting dialysis, and kidney transplantation from 30 percent to 35 percent of all ESRD patients over the duration of the model. [The calculation of the 50 percent target that ASN recommends incorporates other factors.] Achieving these goals would be, in our view, an unmitigated success on behalf of patients while providing sufficient latitude to still allow for individualization of care.

ASN recommends revising the proposed approach to benchmarking in the ETC Model. The proposed rule states:

> *Our intent in future MYs is to increase achievement benchmarks among ETC Participants above the rates observed in comparison geographic areas. By MY 9 and MY 10, in order to receive the maximum achievement score, we are considering that an ETC Participant would have to have a combined home dialysis rate and transplant rate equivalent to 80 percent of attributed beneficiaries dialyzing at home and/or having received a transplant.*

As stated above, we do not believe 80 percent is achievable. Assuming 900,000 patients with treated ESRD at the end of the demonstration project, achieving 80 percent would require a drop of almost 280,000 in the number of patients treated with

in-center hemodialysis, an increase in the number of home dialysis patients by 260,000, and an increase in the number of transplant patients by 185,000 compared to 2016 data. In addition, as is utilized in other benchmarking quality efforts like the ESRD Quality Incentive Program (QIP) program, benchmarking can be achieved through achievement and improvement thresholds, whereby performance is rewarded for continuous quality improvement over time.

We want to avoid unfairly penalizing programs that have already been successful at increasing rates of home dialysis and transplant and are therefore "topped out" while rewarding programs that have had worse performance on this importance aspect of care to date. Achievement and improvement thresholds should be reasonably achievable.

Likewise, we urge CMMI to not implement a forced bell curve approach that could apply penalties to as much as 30 percent of participants regardless of their improvement and achievement scores. A forced bell curve is not essential to achieve the program's goals of increased patient choice among in-center, home, and transplant. And, in fact, may run counter to that goal by taking away resources from practices at the very moment those practices need them for investment to make these outcomes possible. ASN also requests CMMI clarify future benchmarking transparently in the final rule and future rulemaking and to also request comments on the final rule as it did with the Quality Payment Program (QPP).

2) Empowering Patients and Care Teams to Evaluate the Range of Treatment Options

The proposed model rightly recognizes the critical importance of access to expanded modality choices – particularly home dialysis and transplantation – to improve patient outcomes. Current reimbursement and delivery systems for kidney care often do not emphasize patient choice, tending to default to in-center hemodialysis (HD). In contrast, the proposed ETC Model explicitly aims to make accessible and expand the use of all care options so that patients, together with their care partners and clinical care teams, can select the option that is best for them.

The patient is at the center of this decision-making process and should be empowered to determine which modalities they pursue in treating their kidney failure, including the decision to not pursue a replacement modality and elect for comprehensive conservative medical management. The modalities highlighted in the ETC model include home dialysis and transplantation, both of which are underutilized in the United States.

> *Home dialysis patients can dialyze from the comfort of home, giving them better control of their treatment schedules, more time for themselves, their families, their jobs, and the activities they enjoyed before starting dialysis.*[1]

[1] https://www.davita.com/treatment-services/home-dialysis

While home dialysis does have advantages for some patients, no single modality is the right fit for all patients. As stated above, ASN is deeply concerned about patients who are housing insecure. The strong negative penalties in the ETC Model could create undue pressures on nephrology health professionals to consider directing this vulnerable population to home dialyze when in-center care may be a preferable modality due to their unstable housing situation.

Additionally, the ETC model would disproportionately penalize Managing clinicians and facilities that care for this vulnerable population if they are unable to achieve the desired rates of home dialysis because they are appropriately individualizing care for people with unstable housing. ASN believes that one of the biggest safeguards to this potential scenario is a major reduction in the penalties and thresholds with the goal of creating latitude to appropriately individualize care.

While we believe that reducing targets and benchmarks will provide guardrails for patients, we also agree with CMMI that there needs to be risk adjustment. ASN recommends that CMMI add to its risk adjustment neighborhood census data linked at the zip code level. For example, an index of neighborhood socioeconomic status (SES) was computed from U.S. Census block-group data linked by ZIP code according to the Agency for Healthcare Research and Quality (AHRQ) as = 50 + (0.11*median household income score) + (0.08*median property value score) + (-0.10*% below federal poverty line) + (-0.08*% unemployed) + (0.10*% college graduate) + (-0.11*% education <12th grade) + (-0.07*% crowded household)[2]. CMMI should incorporate into its risk adjusting the lower SES levels at the zip code level.

CMMI should encourage ETC participants to use shared decision-making tools in selecting modality choices, including those that currently exist and others that may be in development. Incorporation of high-quality decision aids could empower patients to make treatment choices tailored for their needs and preferences and allow patients to re-evaluate these options regularly as their circumstances change over time while protecting the patient role.

In the proposed rule, CMMI writes:

> *We considered including beneficiaries whose dialysis modality is self-dialysis or temporary PD furnished in the ESRD facility at a transitional care unit in the numerator, given that these modalities align with one of the overarching goals of the proposed ETC Model, to increase beneficiary choice regarding ESRD treatment modality. However, these modalities lack clear definitions in the literature and delivery of care for these modalities is billed through the same*

[2] Agency for Healthcare Research and Quality. Creating and Validating an Index of Socioeconomic Status. (Accessed June 28, 1010 at http://www.ahrq.gov/qual/medicare indicators/medicareindicators 3.htm.)

codes as in-center HD, making it impossible for CMS to identify the relevant claims.

Additionally, ASN recommends including in-center, self-care patients in the numerator of home patients for a given clinic/program/geographic area for a defined period of time. We consider self-dialysis or temporary PD furnished in the ESRD facility such as urgent start PD as an important part of the "treatment choices" for patients. These activities can serve as a bridge to home dialysis, a period of adjustment and confidence building, and a mechanism for support for patients who need an alternative to their normal home dialysis.

ASN proposes the following definition of self-care:

Dialysis performed with little to no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in 494.100 of the Conditions for Coverage for End-Stage Renal Disease Facilities. At a minimum, a self-care patient should:

- *Set up and take down the equipment used in the treatment*
- *Respond to alarms during treatment*
- *Manage access site pre- and post-treatment*
- *Take and record their own weight and vital signs*

By expanding the current definition of self-care in regulation and including in-center, self-care patients in the numerator of home patients for a given clinic/program/geographic area and time, the model accounts for increased access to modality choices for patients. We propose using the existing condition code for "self-care in unit" (code 72) as defined in section 50.3 of Chapter 8 of the Medicare Claims Processing Manual to track self-care patients.

One of the most important goals of this model is to identify those patients who are able to pursue home options, help them (and/or their care partners) become proficient and comfortable with home dialysis technologies, and monitor their outcomes. We believe the above recommendations will help the model achieve this important objective.

3) Guaranteeing Access to Home Dialysis Programs

Enhancing patient access to kidney failure treatment modalities (and the education needed to properly evaluate those choices) is a key goal of the ETC model, and one ASN strongly supports. CMMI proposes facility level scoring to better incent:

ESRD facilities within the same company in the same HHR to provide the same level of care to all attributed beneficiaries.

However, ensuring reasonable patient access to a home dialysis program does not require that every dialysis facility offer a home dialysis program. ASN is concerned that incenting every facility to offer a home option will not actually result in better outcomes for patients. Rather, we believe patients will be best served if the emphasis in the ETC

model is on patient *access* to home dialysis, instead of on whether every facility offers home dialysis.

Therefore, CMMI should aggregate all facilities regardless of corporate ownership or affiliation to a geographic level such as the hospital referral region (HRR) when assessing access to home dialysis. We also recommend eliminating the reliability adjustment. The proposed rule does not contain sufficient details to fully evaluate the reliability adjustor and sows doubts in the minds of some as to how it will function. In addition, aggregating to a geographic level (such as the HRR) eliminates the need for a reliability adjustment.

An approach focused on access versus a facility-level approach is geared to providing access to the best home dialysis programs possible within a given region as opposed to incentivizing the creation of micro-programs across an area, which we believe the current proposed reliability adjuster without aggregation would do – intentionally or unintentionally. This latter approach may have the unintended consequence of creating programs that are effectively too small to be successful, or where the supply of home dialysis nurses and other resources may not be sufficient to sustain the program. A facility-based approach also does not account for patient movement within the network of care.

ASN recommends CMMI examine the option of excluding companies or institutions that do not provide in-center care in their clinics in the geographic region from participating in the model unless they are contractually aligned with providers that offer in-center dialysis. If a provider primarily cares for home patients in an HRR, that provider will automatically be in the top tier for payment and will artificially skew the home dialysis rate for other providers in the HRR. Allowing and encouraging providers to contract with home dialysis providers as a virtual group mirrors what is currently allowed in the Quality Payment Program (QPP).

The following are examples in which the facilities and practices have been de-identified:

A) *A patient seen at X health provider by a nephrologist for late stage CKD is waitlisted for a kidney transplant and is about to start dialysis. X health provider has a 5-star rated in-center HD program, but, after discussing with the nephrologist, the patient choses to start peritoneal dialysis. The dialysis program at X health provider has partnered with a separate company that operates a home dialysis-only clinic to provide home dialysis therapies at a nearby facility. Originally, X health provider had a smaller home dialysis program that lost money and the partner program was operating successfully with very good patient outcomes.*

   Despite not having its own home peritoneal dialysis unit, by contracting with the company that has experience and expertise in home dialysis, X health provider was able to provide immediate access to high quality, timely, low-cost home dialysis care which was in the patient's best interest. In addition, this type of contract allows for continuity of care such

that the treating nephrologist continues to follow the patient from CKD through home dialysis and potentially through transplant with patients being able to be seen two out of three monthly visits using telehealth for their monthly nephrology visit.

B) *A patient was seen and followed at Hospital Z, which has a home program but not an in-center dialysis program. The patient was initiated on in-center hemodialysis and received HD at a local facility where Hospital Z nephrologists did not see patients. The nephrologist, nurses and educators at this HD facility worked diligently with the patient, providing education regarding home dialysis. The patient elected to undertake home dialysis and was transferred back to the care of Hospital Z clinicians and Hospital Z's home program rather than a chain affiliated program of the HD facility.*

These examples highlight the interactions that exist among different dialysis providers and among different clinician practices. In both of these scenarios, the patient was empowered to perform home dialysis. The first example demonstrates that programs can contract with otherwise non-affiliated facilities to provide home dialysis without having to start their own home dialysis center, without delays, an increase in cost, or need for the patient to start in-center dialysis. The second scenario exemplifies effective use of existing home dialysis infrastructure, and one in which the HD facility and the HD clinician would effectively lose the patient from their numerator by referring the patient back to their prior institution and care team.

4) Incentivizing and Investing Wisely in the ETC Model

ASN believes the goals of the AAKH initiative and the proposed ETC model represent a necessary paradigm shift in the kidney care delivery system that has existed for nearly half a century. In order to realize this transformative goal and avoid the unintended consequences described already in this letter, we believe there must be both appropriate adjustments that are not overly punitive and more up-front investment to make possible the desired achievements in increased home dialysis and transplantation rates. The patient benefits and cost savings to Medicare that can be realized by placing greater emphasis on home dialysis and kidney transplantation cannot be achieved by cutting costs alone in the early years of the ETC model. The truly significant savings to Medicare under the proposed model derive directly from improved outcomes, less hospitalization, more transplantation, and fewer years of dialysis – results that will require investment in order to achieve.

We believe CMMI must:

- Reduce Performance Payment Adjustment (PPA) and align it with penalties in the ESRD Quality Incentive Program (QIP)
- Invest in the Home Dialysis Payment Adjustment (HDPA) at 3-5 percent annually for the life of the model
- Make the model an Advanced Alternative Payment Model (AAPM)

The Performance Payment Adjustment (PPA): CMMI should reduce the magnitude of the PPA to lower penalty levels below the proposed up to 11% for managing clinicians and should replicate the penalties in the ESRD QIP with a maximum 2% penalty. The ETC model constitutes a fundamental shift in the business of nephrology, away from default in-center HD and toward adoption of more modality choices for patients. However, many stakeholders in the community have characterized the ETC model as punitive and diminishing patient choice by promoting home dialysis modalities that many patients may not be good candidates for or want. ASN members have expressed strong reservations and concerns about the 11percent penalty clouding the critical modality selection decision between patients and their nephrologists.

Fundamentally, we perceive the ETC model as having the explicit goal of increasing patient choice. But to ensure that nephrologists feel they are able to help patients make choices based on what is best for each individual patient, the magnitude of PPA penalties must be reduced. Reducing penalties in the PPA protects the nephrologist from receiving a financial penalty for doing what is right for their patients and bolsters the patient physician relationship. CMMI needs nephrologists as partners in the fundamental transformation of nephrology care and reducing the proposed penalties will be a critical step in this direction.

The Home Dialysis Payment Adjustment (HDPA): CMMI should invest sufficiently in the Home Dialysis Payment Adjustment (HDPA) to ensure success for ETC participants and patients. The 3 percent, 2 percent,1 percent payment structure of the HDPA is a laudable concept, but financially underpowered to support the practice transformation needed to establish robust home dialysis programs. ASN recommends a 3-5 percent positive adjustment for the life of the model similar to participants in an Advanced Alternative Payment Model (AAPM).

At present, only approximately half of freestanding dialysis facilities operate a home dialysis program. If the desired increase in home dialysis prevalence is to occur, many dialysis organizations and nephrologist practices will need to invest in the infrastructure and personnel to either expand existing programs or create and support new programs to meet demand. Allowing providers to contract virtual groups with organizations that focus primarily on home dialysis could relieve some of these challenges.

The reality is that most facilities or practices do not have excess space in which to open a new home dialysis program. Also, one of the biggest costs will be hiring and training more nurses, particularly more PD nurses. Under the ETC, these nurses will be in high demand and will represent a large percentage of new costs for providers – costs that the HDPA as currently structured will not address.

Additionally, to increase home dialysis utilization robustly, individuals with significant comorbid conditions will need to be included. These individuals have more medical care needs and may be less self-sufficient, for instance individuals with amputations due to diabetes or individuals with visual impairment or individuals with frailty. For these individuals to succeed at home dialysis, intensive early home assistance as well as

ongoing maintenance home support is likely to be needed, including options for respite assistance when family care partners cannot be present.

Accordingly, home-assist efforts should be supported as needed since these resources will be critical in enabling ETC participants to provide the greater in-home training and support key to preparing or transitioning patients, when appropriate, to home dialysis. This transition could occur through direct payments for home health services by utilizing savings to expand the Medicare home health benefit to include a home nursing provision of dialysis care or through the provision of direct rebates to patients to subsidize caregiver costs in the home.

The only absolute contraindication to PD is absence of a functional peritoneal membrane; however, many relative contraindications exist that require additional effort to overcome. Additional assistance directed towards the patient in the home will foster success in overcoming these hurdles.

The study "Impact of contraindications, barriers to self-care and support on incident peritoneal dialysis utilization"[3] found that family support was vital to increasing PD as the chosen and utilized dialysis modality:

> *Family support was associated with an increase in PD eligibility from 63% to 80% (P = 0.003) and PD choice from 40% to 57% (P = 0.03) in patients with barriers to self-care. Family support increased the incidence of PD utilization from 23% to 39% among patients with barriers to self-care (P = 0.009). When family support was available, 34% received family-assisted PD, 47% received home care-assisted PD, 12% received both family- and home care-assisted PD, and 7% performed only self-care PD. Incident PD use in an incident end-stage renal disease (ESRD) population was 30% (147 of the 497 patients).*[4]

Clearly, barriers to home dialysis and the availability of family support are key factors to PD utilization and should guide CMMI's estimations of PD rates and the need for providing home assistance. All of these factors are why CMMI should calculate the HDPA as an ongoing payment for the life of the model.

Advanced Alternative Payment Model (AAPM): Within the QPP, a payment model must meet three requirements in order to qualify as an AAPM. The proposed ETC Model contains two of those three criteria: payment based on quality metrics similar to MIPS and two-sided risk. The third is that the model would need to "require participants to use certified EHR technology."

We recommend CMMI investigate making the ETC an AAPM—which would require the use of certified EHR technology—with one caveat: we believe the most essential of ASN's payment recommendations is to reduce the penalties under the PPA. Reduction

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[3] Nephrol Dial Transplant. 2010 Aug;25(8):2737-44. doi: 10.1093/ndt/gfq085. Epub 2010 Feb 25

[4] https://www.ncbi.nlm.nih.gov/pubmed/20189930

of the penalties under the PPA is our priority if all of these items – reduction of the PPA, increase of the HDPA, and making the ETC model an AAPM – are not possible in combination.

Additionally, in a brief comment in the proposed rule, CMMI writes:

> *The payment adjustments made under the ETC Model would be counted as expenditures under the Medicare Shared Savings Program (MSSP) and other shared savings initiatives.*

Any positive payment adjustment earned by the ETC Participant should remain a positive payment adjustment. This proposed action could nullify the ETC positive payment adjustment by penalizing the participant in an MSSP which seems unfair as the participant is being penalized in one program for performing well in another. We recommend CMMI remove this provision.

Contraindications and Barriers

Relative contraindications and other barriers to home dialysis must be factored into the ETC Model. Targets for PD utilization may be difficult to achieve because many older patients have relative contraindications to PD or barriers to self-care leading to the need for home-assist efforts or the removal of such patients from the denominator.

The study "Impact of contraindications, barriers to self-care and support on incident peritoneal dialysis utilization"[5] summarized its findings thusly:

> *One hundred and ten (22%) of the 497 patients had absolute medical or social contraindications to PD. Of the remaining 387 patients who were potentially eligible for PD, 245 (63%) had at least one physical or cognitive barrier to self-care PD. Patients with barriers were older, weighed less and were more likely to be female, start dialysis as an inpatient and have a history of vascular disease, cardiac disease and cancer.*

The ETC Model should account for interruptions or delays in PD for healthcare reasons without penalizing ETC participants. For example, a patient who was using PD as their kidney replacement modality but requires abdominal surgery and must continue in-center HD until they have sufficiently healed to resume PD should be counted as a home dialysis patient in the ETC participant's numerator.

The following are real examples from ASN members:

A) *A current PD patient of developed colon cancer. He required a partial colon resection and surgery to treat an isolated liver metastasis. He was treated with hemodialysis for several weeks before the surgery, and he remained on hemodialysis following the surgery to permit healing and to allow for use of*

[5] Nephrol Dial Transplant. 2010 Aug;25(8):2737-44. doi: 10.1093/ndt/gfq085. Epub 2010 Feb 25

specific chemotherapeutic agents to treat this cancer. He transitioned back to PD after five months of hemodialysis around this episode.

B) *A patient required a nephrectomy for a five cm renal cell carcinoma. She was treated with hemodialysis for approximately six weeks around this surgery before transitioning back to PD.*

C) *A patient who was heavily immunosuppressed following a non-kidney solid organ transplant developed fungal peritonitis. His PD catheter was removed, and he was treated with HD for 6 weeks. A PD catheter was replaced, but PD was unsuccessful. On laparoscopy, he had extensive adhesions and, despite lysis of adhesions, was unable to successfully resume PD and returned to HD.*

These are common circumstances. We recommend CMMI allow for at least 90 days of this type of classification of patients in transition. Additionally, should this patient develop other conditions, such as abdominal scarring and remain hemodialysis dependent, they should remain excluded from both the numerator and denominator. However, should the patient be able to return to PD, they would return to both the numerator and denominator. This will provide an incentive to troubleshoot potentially surmountable issues with PD while avoiding inappropriately compelling patients to return to PD.

5) Increasing Access to Transplantation

The AAKH initiative aggressively takes on the challenging issues posed by the tremendous unmet patient need for transplantation in the face of an insufficient organ supply. The initiative has a stated goal of doubling the number of kidneys available by 2030. We applaud this ambitious goal and, on behalf of the entire community, including our patients, want to assist HHS in reaching this goal.

While many of the policy levers the administration intends to use to increase the supply of deceased donor organs and to enable more living donation will be addressed in other rulemaking efforts and on Capitol Hill, we are strongly supportive of the learning collaborative "that focuses on disseminating best practices to increase the supply of deceased donor kidneys available for transplant." We stand ready to work with CMMI to ensure that the learning collaborative can reach its full potential.

In addition, we strongly support the use of an actual transplant rate as a metric in the ETC model. This approach will require both nephrologists and dialysis organizations to take a much more proactive, focused approach to improving patient access to transplantation in ways that they have not been previously asked to do. This approach also constitutes a fundamental shift and will necessitate greater cooperation with patients, their families and loved ones, transplant centers, Organ Procurement Organizations, and other stakeholders.

While we acknowledge that there are some aspects of the transplant process that are out of the control of nephrologists and dialysis organizations – such as the total number

of deceased donor organs available for transplant nationwide or the suitability of a patient's family and social network to serve as living donors – there are many aspects of the process that can and should be in their control – such as how they educate patients and families about living donation and how effectively they interact with transplant centers. The nephrology care community can and should make transplantation a more central part of routine care, practice, and modality selection than presently occurs, and a risk-adjusted transplant rate metric is an appropriate tool to engender this change.

6) Delaying the Start Date of the ETC Model until later in 2020 and Implementation of Downside Adjustments Until Conclusion of MY Three

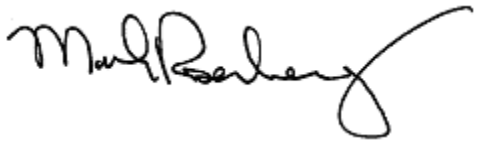
CMMI invited comment on delaying the start date of the proposed model from January 1, 2020, to April 1, 2020, to allow the agency more time to prepare the model. ASN strongly urges CMMI to adopt the delayed start of April 1, 2020, to allow all ETC participants to prepare for the program and increase the likeliness of success. In addition, we strongly urge the agency to delay downward payment adjustments until the conclusion of MY three which ends December 31, 2021, to allow participants to fully operationalize their programs and begin to experience longer term results such as transplant.

7) Using Proposed Rulemaking and Additional Comment Opportunities

ASN recommends that CMMI issue proposed rulemaking annually to include evaluations of the program and adjustment for "lessons learned" as the model progresses. We additionally request a second round of comments following revisions made in response to the comments on the current proposed rule by the kidney community as was done with the QPP. We request these items to maintain an iterative process, but they should not be used to delay the program.

Again, thank you. ASN stands ready to assist CMMI, the Department of Health and Human Services, and the society's members in every way possible to ensure this important effort succeeds. To discuss ASN's feedback about the proposed rule or strong support for the AAKH initiative, please contact me at (612) 626-9596 or rosen001@umn.edu.

Sincerely,



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