

June 27, 2016

Andrew Slavitt  
Acting Administrator, Centers for Medicare and Medicaid Services  
Room 445–G  
Hubert H. Humphrey Building,  
200 Independence Avenue, SW  
Washington, DC 20201

Re: Proposed Rule for the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models, CMS-5517-P

Dear Acting Administrator Slavitt:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments regarding the April 25, 2016 proposed rule for the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). ASN represents nearly 16,000 physicians, scientists, nurses, and other health professionals dedicated to treating and studying kidney diseases to improve the lives of people with kidney diseases. ASN is a not-for-profit organization dedicated to promoting excellence in kidney care. Foremost among the society's concerns is the preservation of equitable patient access to optimal quality chronic kidney disease (CKD) and end-stage renal disease (ESRD) care and the integrity of the patient-physician relationship.

ASN appreciates CMS's commitment to a thoughtful and transparent rulemaking process to implement MACRA. The proposed rule clearly involved a tremendous level of effort by CMS and HHS to propose a Quality Payment Program (QPP) that fulfill Congress' goals to:

- End the Sustainable Growth Rate (SGR) formula for determining Medicare payments for health care providers' services.
- Develop a new framework for rewarding health care providers for providing better rather than more care.
- Consolidate existing quality reporting programs into a single system.

ASN considers the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) to be a significant improvement over the SGR formula and commends the Agency for the policy principles that shape the QPP. ASN appreciates the opportunity to provide comments about the proposed rule; the society hopes that the recommendations in this letter, summarized below, are helpful to CMS as it implements this important new program:

- CMS should develop a robust outreach and education strategy to help clinicians understand the new payment system, decide which payment pathway makes the most sense for them, and prepare their practice to participate successfully in that pathway.

- ASN urges CMS to monitor and evaluate the effects of the QPP on patient outcomes and access to care in as close to real-time as possible to identify any potential unintended consequences.
- ASN believes that an additional six-month period is needed to educate clinicians and recommends that CMS delay the start of the performance period until July 1, 2017.
- CMS should use its resources in an active effort to continually improve the risk adjustment methodology employed within MACRA implementation, particularly concerning the quality measure component of MIPS.
- ASN stands ready to work with CMS and other stakeholders to address the limited number of meaningful quality measures in the nephrology space.
- ASN recommends the following modifications to the proposed MIPS program:
  - Adjust the resource use component of MIPS down from the proposed 10 percent in the first performance period.
  - Increase the number of proposed Clinical Practice Improvement Activity categories that qualify as “high value.”
  - Implement less stringent standards for the Advancing Care Information category of MIPS.
- ASN is concerned that too few APMs—and particularly, too few Advanced APMs—exist as options for specialists, including nephrologists. CMS should utilize every lever available to expand APM and Advanced APM opportunities, including:
  - Considering modifications to reduce the level of required risk for physician-focused models.
  - Enabling CMMI to test significantly more models than at present, in order to facilitate the goal of creating as many options as possible for clinicians to participate in APMs and Advanced APMs.
- ASN believes CMS’ proposed definition for Medical Home Models is overly narrow, and should be expanded to allow subspecialists in internal medicine, including nephrologists, who serve as principal care providers to participate in and form specialty care medical homes.
- The independence of the patient-physician relationship, and clinician latitude to individualize patient care, must be preserved and should be an important consideration in the design and selection of APMs.

### **Implementing the Final Rule**

The QPP will have ramifications across the practice of medicine, affecting the practices of hundreds of thousands of clinicians, who care for tens of millions of Americans. Given these broad implications, it is incumbent upon CMS and the medical community to collaborate to implement a system that delivers the highest quality care for patients. ASN appreciates that CMS understands that clinicians are a diverse group and that no practice groups are identical. This heterogeneity elevates the complexity inherent in designing a system that can apply to all clinicians and that positively impacts the care that they provide.

Accordingly, to successfully implement the final rule and to position the QPP for success in years to come, ASN urges CMS to develop a robust outreach, education and feedback strategy to help clinicians understand the new payment system, decide which payment pathway makes the most sense for them, prepare their practices to participate successfully in that pathway and inform CMS on successes and pitfalls.

Due to the heterogeneous nature of nephrology care and the complex needs of kidney patients, nephrologists typically provide medical care in multiple settings. The scope of nephrology practice includes caring for complicated hospital inpatients; following a diverse outpatient population with chronic kidney diseases, hypertension, kidney stones and other kidney related conditions including kidney transplant recipients and donors; and managing a modest number of very complex dialysis patients, often at multiple dialysis facilities. Additionally, many of these patients have multiple chronic conditions and psychosocial needs, heightening their risk of requiring acute care. Nephrologists can be solo practitioners, members of small subspecialty practices, employees of large health care delivery systems, members of large multidisciplinary practices, or participants in just about any other practice model. Given this complexity, ASN believes that the final rule should clearly and concisely:

- Provide examples of how various types of clinicians, especially subspecialists such as nephrologists, who treat patients with varying degrees of sickness and complexity in multiple types of facilities, might approach the pathways available in the QPP.
- Provide guidance regarding the need to participate in MIPS since eligible clinicians (ECs) will not know if they are in a qualifying APM until after data from a reporting period is analyzed.
- Provide guidance on the degree of involvement needed for a subspecialist to be considered as a participant in an APM and prospective assessment of likely APM qualification.
- Provide guidance on attribution as it pertains to subspecialists.

ASN intends to complement and amplify educational programs developed by CMS with its own educational tools. In order to allow sufficient time for education, ASN strongly suggests that CMS provide a six-month period for the education and preparation of its clinicians, and the hundreds of thousands of other clinicians across the country governed by the new QPP. Accordingly, ASN recommends that the performance period begin July 1, 2017. ASN believes that clinicians will need this time period to be educated about the contents of this expansive new system and to align their practices with the principles and details in the final MACRA rule, so as to be prepared to deliver the best patient care possible in the new QPP.

### **Merit-based Incentive Payment System**

ASN commends the MIPS's goal of better aligning physician reimbursement with quality and value. The society appreciates that a single program, MIPS, will replace three separate programs (EHR Meaningful Use (MU), the Value-Based Modifier (VM), and the Physician Quality Reporting System (PQRS)). ASN offers comments on the four MIPS program categories and looks forward to continuing to work with the Agency as it shapes the details of this new program moving forward.

In general, the society believes that applying the proposed rule to subspecialties requires a greater effort to align policy and practice than in primary care. ASN recommends that CMS take an active and transparent role in monitoring and educating subspecialists within the QPP and, when necessary, make programmatic adjustments. As may be the case for many other subspecialists, nephrologists not participating in large healthcare systems which have pre-existing capacity to monitor performance and make real-time adjustments early in a performance period are likely to find adapting to MIPS challenging, with the potential consequence of distracting clinicians from focusing on the needs of their patients.

This is particularly true for nephrologists who treat patients in multiple disparate settings with varying case mix and resources. As discussed above, many nephrologists see patients at several hospitals as well as at multiple dialysis units (that currently are excluded from meaningful use) and in independent outpatient offices; accordingly, data on their patients could easily come from five or more independent facility settings. ASN expects that these clinicians in particular will require assistance in understanding and approaching the pathways available in the QPP.

ASN also believes that the reporting language needs clarification and better definition of options for nephrologists who practice in multiple settings. The society strongly urges CMS to provide illustrative examples of options for nephrologists based on actual sample clinical practices. In addition, ASN recommends that CMS allow the creation of virtual groups in the first performance period.

### **MIPS Category #1: Quality**

ASN has a longstanding policy of encouraging emphasis on outcomes measures, as opposed to process measures, when possible, directly reflecting the quality of care patients actually receive. ASN commends CMS for reducing the quality measures reporting requirements of nine or more measures to six with one cross-cutting measure and—where an outcome measure is applicable—one outcome measure. The society believes the option to report on another high priority measure if no outcome measure is available is an important element. In addition, ASN welcomes the removal of the requirement that the measures selected must span multiple domains of the National Quality Strategy (NQS) domains. The society believes these steps will lead to higher quality of care and more meaningful data.

ASN recommends that CMS require that reporting mechanisms include the ability to stratify the data by demographic characteristics noted in the RFI, such as race, ethnicity, and gender. The society also recommends that CMS add age to the list of characteristics. Social determinants of health (over which physicians have no control), such as behavioral health issues, influence people's ability to manage their chronic disease. It would be an interesting aspect for CMS to explore the relationship between such determinants and patients' outcomes in the context of the Quality category.

ASN is concerned about the paucity of meaningful, nephrology-based quality measures specifically for nephrologists. Members of the society have communicated with ASN that there are too few measures for nephrology in general and almost none for transplant nephrologists. While there are many facility level dialysis measures, these measures are not designed to apply to individual clinicians. Furthermore, the measures that do exist for nephrology care at the physician level may not be adequately case mix adjusted to apply to relatively low volume individual clinicians (nephrologists may have 20 to 80 Medicare dialysis patients; one or two outliers could affect performance on a quality measure, particularly among the many nephrologists at the lower end of this patient census).

ESRD, as the name indicates, is the end-stage of kidney failure. The primary goal of nephrology clinicians is to keep patients healthy, high-functioning and off dialysis. When kidney replacement therapies are needed, the goal is to match a patient to their preferred therapy, including comprehensive conservative (non-dialysis) care. Unfortunately, achievement of this quality of care lacks any measures, as there are few if any meaningful outcome measures directed to nephrology clinicians at this time, even when they are providing good care. This limitation in MIPS will make participation in the program difficult for nephrologists. ASN would

be pleased to work with CMS and other stakeholders in developing meaningful measures for nephrologists.

CMS's new proposals that increase the requirements to achieve data completeness criteria for quality reporting are concerning to ASN, especially since physicians who do not meet the proposed criteria would fail the quality reporting component. The proposed MACRA rule states that:

- For clinicians reporting using QCDRs, EHRs, or qualified registries, physicians/groups must report on at least 90 percent of the patients that meet the measure's denominator criteria, regardless of the payer.
- For clinicians using claims reporting, they must report on at least 80 percent of the Medicare Part B patients for which the measure applies.

The society recommends that CMS not take this step. Instead, ASN recommends that CMS maintain current levels of data completeness at 50 percent. As ECs strive to align their practices with the multiple new elements embodied in the QPP, ASN believes the increased data completeness requirements will add an undue burden on clinicians at this time of transition, particularly given the multiple practice settings, including dialysis facilities that are not included in meaningful use requirements. The burden is further exacerbated by the proposal to include all patients – not just Medicare patients – in the first reporting category. Additionally, requiring this level of completeness makes it virtually impossible to upgrade or change a medical records infrastructure and still achieve the proposed reporting levels in the proposed performance period.

CMS has presented several questions for comment regarding when, if, and how a facility's performance might be attributed to an EC for quality reporting, resource use reporting, or both, and indicates that this option would not be available in the first year. Given this planned delay, ASN encourages CMS to seek input from subspecialties, including nephrology, whose clinicians practice in facilities that are not their own. The society urges CMS to engage in a transparent process where nephrologists, and other subspecialties, can jointly shape the answer to this challenge.

As shown in table 62 in the proposed rule, nephrologists are among the top specialties in charges per clinician, suggesting that nephrologists may be at particularly high risk, particularly given the high likelihood of imprecise measure performance results due to risks associated with a handful of patients possibly skewing performance data. Particularly as CMS explores options to possibly attribute facility scores to clinicians, all clinicians should have a voice in shaping how performance data will be attributed to them. ASN requests that CMS provide examples of how this may work for the broad spectrum of nephrologists. The society urges CMS to engage in a transparent process where nephrologist, and other subspecialties, can jointly shape the answer to this challenge.

Currently, physician-oriented measures, based on NQF endorsed measures, are insufficient to allow nephrologists ample meaningful reporting measures that indicate the quality of care delivered by individual clinicians. The society requests that CMS offer examples illustrating how nephrologists—including nephrologists who specialize in the care of kidney transplant recipients—can successfully complete the quality component of MIPS within existing measures, including nephrologists who specialize in caring for kidney transplant recipients. ASN would be pleased to work with CMS and other stakeholders in helping to promote meaningful, physician-oriented measures that satisfy these domains.

For nephrologists not practicing in a large healthcare system, there is a single available registry for data dissemination that can cost between \$500 and \$900 to use. ASN requests that CMS account for these expenses in their calculations of the impact of MACRA on clinicians.

The society also urges CMS to identify mechanisms to reduce the two-year time lag between provision of care and when physician payment adjustments. The significant gap does not incentivize higher quality care but rather reduces the utility of the program and makes it harder for physicians to make meaningful alterations in practice based on the quality program information.

ASN participated in the development of the Choosing Wisely recommendations and strongly supports their use in helping physicians and their patients in making informed, individualized decisions. However, the society recommends that CMS not attempt to incorporate these recommendations into the MIPS program. It is possible that some of the Choosing Wisely recommendations will be modified over time as knowledge of “best practices” evolve, and the recommendations are not intended to apply to all patients or be used in every situation. In fact, the initial goal of the Choosing Wisely campaign was to encourage critical, and transparent, discussions between the care teams and patients to come to a patient-centered decision on evaluations and treatment based on current evidence driven best practices.

Finally, ASN notes that the diversity of patient populations, with different degrees of comorbid conditions, frequent health status changes, and varying preferences for care intensity, will make it difficult for all providers, especially those who treat the sickest and most disadvantaged patients, to succeed. Patients with advanced chronic kidney disease, including ESRD, are among the most chronically ill patients in the Medicare population. CMS should identify ways to ensure that the new system does not unintentionally create disincentives that would limit access to optimal care for most vulnerable patients and those with advanced complex chronic illnesses. ASN would be pleased to work with the Agency in this effort.

### **MIPS Category #2: Resource Use**

Under MACRA, “the Act specifies a series of steps and activities for the Secretary to undertake to involve the physician, practitioner and other stakeholder communities in enhancing the infrastructure for resource use management, including for purposes of MIPS and APMs.” ASN welcomes the opportunity to engage in a regular dialogue with CMS to address many of the conditions previously discussed that are unique to nephrology as well as those that may span other medicine fields.

As was described earlier, nephrologists often provide care in multiple facilities, five or more for many clinicians. Those facilities approach resource use differently and have varying case mixes. This situation leads to a very diverse patient case mix, diverse attribution methodologies, and diverse data sources for nephrology clinicians. To appropriately account for resource utilization, multiple factors, including case mix, will need to be considered. Currently, case mix adjusters include the broad categories of ESRD or CKD stage; while this addresses the need of health care systems and primary care providers, this does not address the need that nephrologists have to adjust for case mix, where it will be imperative to differentiate within the ESRD population or within the non-dialysis CKD population when assessing resource use. Since a high proportion of nephrology patients are very high cost, accurately discriminating resource use within this population is essential.

ASN does not believe that the current resource measures fairly adjust for these variables and is concerned that nephrologist will be subjected to undue risk if the resource section of MACRA is implemented as described in the draft rule. ASN recommends an ongoing dialogue be established between CMS, ASN, and other subspecialties to identify methods of sufficiently adjusting measures within chronic conditions as well as to identify pathways through which the nephrology clinician has direct input in the mix and source of measures data used to calculate the resource use section of their Composite Performance Score (CPS) given the inherent heterogeneity of nephrology practices.

CMS discussed using Episode Groups as part of this Resource Use component of MIPS. Notably there are a limited number of episode groups directly relevant to nephrology practice. However, within nephrology, there is the potential to develop episode groups that are meaningful for patients whose care is directed by nephrology providers. Potential episodes that would require further exploration include but are not limited to hospital-acquired acute kidney injury, chronic dialysis initiation, kidney allograft rejection, and comprehensive conservative care for patients electing to not receive kidney replacement therapy. ASN would be pleased to work with CMS to develop these further.

MACRA requires *no more than* 10 percent of MIPS CPS may come from resource use, and, in the proposed rule, CMS proposes that resource use count for this full 10 percent. Due to the issues described above, ASN recommends that CMS give resource use a count as low as feasibly possible, ideally at one percent in 2017.

Of the four existing components of the Value-based Modifier, ASN believes that the “per beneficiary” spending assessment is the most useful evaluation. The society does not have recommendations of other cost or resource use measures at this time, but observes that the baseline for the component “per beneficiary – with specific conditions” will change over time as best practices evolve. ASN notes that, with the proposed application of the Value-based modifier to individual clinicians in 2017, it is imperative to develop adequate within-disease adjustment, to account for the tremendous heterogeneity in patients with kidney diseases. The proposed rule states on page 116: “Based on experience in the VM program, these measures (in Table A) have been determined to be reliable with a minimum case size of 20. Average reliabilities for the acute and chronic measures range from 0.64 to 0.79 for groups and individual MIPS eligible clinicians.”

ASN is uncertain that this is the case across measures, and notes that, within the dialysis realm, ICH-CAHPS, requires a minimum of 30 patient responses. Without specific data showing otherwise for nephrology measures, ASN recommends raising the threshold for the minimum number of patient responses to 30. In the absence of specific data showing otherwise for nephrology measures, ASN is very concerned that the 20 threshold will not be reliable, even with the relatively low (and potentially inappropriately low) reliability threshold of 0.4 that is being proposed.

At present, primary care providers and community-based measures are the peer group/benchmarks in the VM program. ASN strongly encourages the Agency to compare subspecialists to subspecialists, ideally within the same subspecialty, and to use measures that best reflect that subspecialty. ASN additionally requests that, prior to implementation, CMS evaluate reliability thresholds for the minimum number of beneficiaries under the VM-based resource use criteria. ASN would be pleased to provide additional input regarding measures specific to the practice of nephrology and encourages CMS to seek input from the society, nephrologists, and other kidney community stakeholders.

### **MIPS Category #3: Clinical Practice Improvement Activities**

Participation in an APM is a significant commitment, and ASN concurs that it is worth incentivizing. Considering the level of effort to participate meaningfully in care transformation, ASN believes that clinicians who are practicing in APMs should receive more credit in the context of their MIPS score than currently proposed. Specifically, ASN recommends that the CPIA weight be increased closer to 100 percent, and absolutely no lower than 75 percent. Similarly, ASN notes that CMS has proposed that primary care medical homes receive the highest potential CPIA score; ASN encourages the agency to make similar provisions for comparable specialty medical home programs.

CMS should incentivize physician participation in robust clinical data registries that provide feedback and best practices related to quality of care to help drive improvement. The activities related to registries should be reweighted from “medium” (10 points) to “high” (20 points). High-quality registries inherently support high value clinical practice improvement, and these activities should earn physicians the highest amount of CPIA credit. Raising the point value for these activities will allow registries to offer a sufficient number of activities to support its members, which may be particularly helpful in the first year of MIPS when the clinicians will be burdened with many new processes and activities related to MIPS. Under the proposed rule, clinicians in practices with more than 15 physicians would have to report on 6 CPIA activities weighted as medium in order to reach 60 points, creating a heavy burden for physicians to perform and report.

ASN observes that a number of the CPIA activities proposed include aspects of care that are outside of the physician’s control (patient electronic access, patient engagement and health information exchange). A physician’s performance should not be judged on an action required by the patient.

In addition, CMS should recognize relevant performance and quality improvement accredited continuing medical education (CME) as CPIA in MIPS. Accredited CME providers design and evaluate activities that promote new practice strategies, performance of individuals and teams, and patient outcomes. ASN believes inclusion of CME in the list of CPIA activities, in addition to maintenance of certification activities as proposed, would be an appropriate enhancement of MIPS options.

ASN views thoughtful and appropriate expansion of telehealth and related technologies as an integral piece of the transition from fee-for-service care to more comprehensive, alternative payment models. Accordingly, the society was pleased that CMS included telehealth in the CPIA list. ASN encourages CMS to allow health professionals who are implementing telemedicine and remote patient monitoring to count this as part of their successful participation in the CPIA program and to expand this option as telemedicine technology continues to evolve to keep pace with patient-centered innovation.

ASN notes that dialysis facilities and the physicians who care for patients in these facilities engage with Quality Improvement Organizations regularly through the ESRD Networks. The society believes these efforts should qualify as CPIA. Furthermore, the society requests clarification of the implications of ‘population’ within ‘population management’. Within the scope of a nephrology practice, ASN interprets these CPIAs to be applicable to a population of dialysis patients or transplant recipients, for example.

#### **MIPS Category #4: Advancing Care Information**

For the Advancing Care Information (formerly Meaningful Use) performance category, CMS proposes six objectives (and related measures) to comprise the base score for this category. These measures are yes/no or numerator/denominator, and they account for half of the ACI score. Every base measure must be successfully reported in order to earn any points in the ACI category. ASN urges CMS to revise its proposed “all or nothing” approach to the base score. Also, ASN believes that requiring a full year of reporting for ACI increases the burden on physicians and recommends CMS allow physicians to report on a single 90-day period within a year. This is particularly important given that institutions may change their EHRs, affecting continuous reporting ability.

Under the current meaningful use program, more than 50 percent of nephrologists have applied for the hardship exceptions under practice at multiple locations category. This is indicative of the fact that nephrologists do not always have control over whether or not the facilities they see patients in have certified EHR. In recognition of the challenges nephrologists face in this arena due to the nature of their practice, ASN urges CMS to maintain flexibility and account for diversity of practice environments as it finalizes the ACI component of MIPS.

ASN believes that significant opportunities exist to leverage EHRs to improve nephrology care, and hopes that their increased adoption will meaningfully improve patient outcomes in the future. However, in order for EHRs to achieve their potential in advancing care for patients in the context of MIPS (as well as in APMs), physicians and other health professionals need solutions that permit disparate EHRs to interface and provide genuine interoperability. Until EHR technologies achieve better interoperability than currently available, any EHR adoption requirements for health professionals participating in MIPS or APMS will be relatively ineffective at driving improved patient outcomes.

CMS inquiries about what other IT infrastructure could be helpful in achieving the goals of MACRA. Opportunities exist to use EHRs to improve care for patients with kidney disease, and ASN strongly encourages the Secretary of Health and Human Services to work with the technology community to develop the seamless interoperability that health professionals need and patients deserve. For instance, in order to make seamless care transitions and optimal care coordination a reality, it is critically important that EHRs used in hospitals and in nephrology practices effectively and easily interface with and incorporate data from the dialysis providers. Currently, it is burdensome to access EHR data from the dialysis units and vice versa. ASN encourages HHS to pursue solutions that have the disparate EHRs develop interfaces for interoperability. Of particular importance for the care of kidney patients are access to physician notes, medication reconciliation, and other elements of the patients’ basic care plan.

#### **Alternative Payment Models**

ASN commends CMS for the policy principles outlined concerning APMs and strongly supports MACRA’s intent and the Agency’s efforts to transform care delivery systems, emphasizing the quality and efficiency of care for patients. The society is pleased that CMS anticipates continuing to build a portfolio of APMs that collectively allows participation for a broad range of physicians and other practitioners. The creation, testing, and eventual availability, of a broad range of alternate systems to deliver better care will foster the goals of better care, smarter spending, and healthier people. ASN is committed to serving as an engaged partner with the Agency in developing and refining new care delivery models for nephrologists and other ECs.

### **Overview of proposed APM policies**

In light of the complicated nature of the steps proposed to determine whether an EC is a Qualifying APM Professional (QP), ASN urges CMS to develop resources for clinicians to understand the process and identify where they can or might fit into the new system as an EC, QP, Partial Qualifying APM Participant (Partial QP), or EC in a MIPS APM. The society recognizes that CMS proposes to notify ECs whether they qualified as a QP or a Partial QP as soon as possible following the performance period (likely not before the summer of the subsequent year) but any information that CMS can provide up front would be of tremendous value to clinicians.

As discussed earlier, ASN would prefer the performance period to align more closely with the payment period. However, regardless of the time lag eventually selected, the QP performance period should remain parallel to the MIPS performance period for ECs. It is important to maintain the MIPS EC and the QP performance periods the same in order to provide consistency for clinicians who are considering transitioning into an APM.

### **Medical Home Models**

As CMS notes, MACRA establishes “medical home models” as a crucial component of MACRA and within the landscape of models that qualify as Advanced APMs, but does not define a medical home. The agency spells out six criteria to define the elements of a medical home—four of which must be met by a given Medical Home entity—to qualify as such, and ASN supports this list. CMS also proposes that a medical home must include “primary care practices or multispecialty practices that include primary care physician and practitioners and offer primary care services, defined as clinicians affiliated with just eight Specialty Codes.” ASN believes this definition is overly narrow, and should be expanded to include subspecialists in internal medicine, including nephrologists. The society believes that CMS was on the right track by identifying Internal Medicine as one of those eight specialties, and that subspecialties that build upon the foundation of training in Internal Medicine would appropriately facilitate the establishment of medical home models that tailor to the unique needs of specific patient populations.

Among patients with more rapidly progressing kidney disease and patients with advanced CKD, including but not limited to those treated with dialysis and transplantation, nephrology care is critical to optimizing treatment of nearly all health issues in this diverse and chronically-ill population. Indeed, many nephrologists serve as the principal care provider for their patients with kidney disease.

Nephrology medical home models would be well-suited to meet each of the six criteria proposed while providing a specialized care focus, reflecting the needs of people with kidney disease. Nephrologists are specifically trained to manage patients with multiple co-morbidities and, in a nephrology medical home, the nephrologist and nephrology practice would assume primary responsibility of managing related comorbidities and coordinating patients’ access to the multitude of other specialists needed to manage their complex conditions. Effective management of co-morbidities is especially important for patients with earlier stages of CKD, during which proper care coordination by a nephrologist can help slow the progression of kidney disease towards ESRD as well as help prevent the worsening of co-morbidities that are caused or exacerbated by kidney diseases, such as hypertension and heart disease.

ASN recognizes that CMS is not seeking recommendations for models that meet the proposed definition of a medical home that might be tested by CMMI (and one day expanded so as to qualify as an Advanced APM). However, the society hopes that this example is illustrative and

informs CMS's perspective on the value of a broader definition of a medical home model.

### **“Demonstration Thesis” Testing**

ASN strongly concurs with the recommendation that the definition of a model “required by federal law” must have a “demonstration thesis” that it is testing. Moreover, the society urges CMS to ensure that all models tested under CMMI have pre-specified criteria for testing and success that are transparent to the entire community before the initiation of demonstration. This type of approach to evaluating the success of new care delivery models will help ensure the Agency is expanding and rewarding the APMs that deliver optimal quality and efficiency.

### **EC Notification**

As an example of how an ACO in the Shared Savings Program is formed, CMS describes that a list of participating Medicare-enrolled TINs (ACO participants) that includes all ECs as identified by their NPIs, who bill through those TINs, is provided to the Agency. Yet it is unclear how the individual clinician in this example would be notified or reminded that he or she is in fact a part of this APM and therefore potentially eligible to be a QP or Partial QP. ASN urges CMS to develop a robust system of communications with individual ECs to notify them of their own status as a potentially eligible (or not) participant in an APM.

The proposal to post on its website as of January 1, 2017, a list of models that CMS has determined to be APMs, and to announce which new models are proposed to count as APMs in RFAs or proposed rules is reasonable. ASN suggests that CMS develop an equally detailed communications plan to the individual clinicians participating in current APMs and to clinicians whose NPIs are included in applications for future APM entities. Besides a posting on the website, ASN encourages CMS to notify all clinicians of their current status and its implications for the new payment pathways in writing, such as via email or mail in as much advance as possible prior to the start of the first payment period.

### **Advanced APM Criteria**

ASN recognizes that whether an APM is an Advanced APM depends solely upon how the APM is designed, rather than on assessments of participant performance within the APM. Besides being a requirement in the statute, this approach may help encourage entities considering testing a new model of care delivery by becoming an APM to do so. Although ideally every APM would achieve its quality and cost benchmarks, the level of risk and commitment to develop an APM is already significant; decoupling actual performance on the quality metrics from the determination of whether an APM is advanced reduces one risk in the decision to establish an APM. However, the lack of relationship between performance and status as an Advanced APM highlights the imperative need for CMMI to ensure any model being tested is rigorously designed, and monitored and evaluated for unintended consequences throughout its existence. Nonetheless, this approach is one step towards ensuring that as many APMs as possible can flourish, consistent with ASN's goal for as many ECs as possible to have the opportunity to participate as a QP.

Similarly, ASN concurs with the Agency's plan not to add additional performance assessments on top of existing Advanced APM standards for the entity or for participating clinicians, and instead to reward the degree of participation in an APM. The quality performance assessments developed at the time the model was established under CMMI should be sufficiently rigorous to spur improved performance under each model.

### **Use of Certified EHR Technology**

CMS proposes that an Advanced APM require at least 50 percent of ECs who are enrolled in Medicare (or each hospital if hospitals are the APM participants) use the certified health IT functions outlined in the proposed definition of CEHRT to document and communicate clinical care with patients and other health care professionals, in the first year of the program. In the second year, the requirement is proposed to increase to 75 percent.

As articulated previously in this letter, ASN believes that setting stringent CEHRT adoption requirements at this time—considering the limited interoperability and patient-centered functions of most EHRs—is unlikely to meaningfully improve patient care and may distract from other more important goals. While large, integrated health systems may more easily achieve the proposed Advanced APM adoption levels of 50% and 75% in the first and second years, this standard would present a difficult barrier for even slightly smaller practices and entities seeking to form Advanced APMs. This fact is particularly true for nephrologists, reflecting the multitude of locations in which they practice and the lack of EHR technologies in many of those environments, to say nothing of the lack of interoperability between those environments. ASN encourages CMS to implement lower thresholds across all Advanced APMs, and in particular to consider reduced thresholds for APMs that include a nephrology-specific focus.

### **Comparable Quality Measures**

ASN recognizes that CMS is statutorily obligated to hold APMs accountable to “comparable” quality standards to MIPS and appreciates the Agency’s thoughtful approach to this requirement. ASN has encouraged parsimony in measure reporting requirements and an emphasis on fewer, outcomes-based measures and is pleased that CMS’s proposals regarding comparable quality metrics for APMs are generally in agreement with these principles.

In designing APMs, CMMI (and, in the future, the P-TAC) should have the latitude to base payment on quality measures that meet the goals of the model and assess the quality of care provided to the population of patients that the APM participants are serving. Provided the CMMI and P-TAC processes are working properly, an additional layer of quality measures is not likely to help patients in a meaningful way. ASN concurs with the agency that APMs that focus on patients with specific clinical conditions, such as kidney diseases, would have valid reasons for including different quality measures than those that target more general populations. The society also recognizes the utility of measures that could be used across APMs and MIPS to reduce the EC’s reporting burden when switching from one program to the other.

Consequently, ASN supports CMS’s proposal that the quality measures on which the Advanced APM bases payment must include at least one of the types of measures listed on page 474 of the proposed rule, provided that they have an evidence-based focus and are reliable and valid. The society also commends CMS for proposing to establish a new Innovation Center quality review process.

As highlighted by the example of the Influenza Immunization quality measure used in the ESRD Comprehensive Care Initiative, this approach may facilitate use of more appropriate measures for specific patient populations and create appropriate flexibility for APMs. Moreover, the ability to test and fully validate new measures within the context of an APM’s demonstration would promote the development of additional measures that may help bring value to both patients and the healthcare system. ASN supports the proposal to establish an Innovation Center quality review process. Use of QCDR measures, as proposed, is also reasonable.

Consistent with ASN's general preference for reporting of outcomes measures instead of process measures, the society believes CMS's recommendation that APMs include a single outcome measure included in the MIPS program is preferable to any other strategy to align APMs with MIPS for purposes of quality assessment. Indeed, ASN would hope that most if not all models being tested include at least one relevant outcome measure for the patient population.

### **Financial Risk**

Reflecting the society's belief that the goals of identifying and testing new ways to coordinate care and deliver value within the context of APMs are crucial objectives for CMS and the U.S. healthcare system overall, ASN urges the Agency to develop standards for APMs that maximize options for physician participation and opportunities for patients to receive value-based care. However, ASN is concerned that the definitions and levels of financial risk proposed in this rule will permit only the largest and/or the most advanced practices and systems to participate in APMs, potentially jeopardizing the momentum towards broad adoption and testing of new models. While supportive of the shift to these new types of care delivery models, the society believes CMS should work to ensure that smaller physician practices have pathways forward to enter such advanced payment and care delivery models of the future. It is unclear whether many, if any, such pathways would exist given the levels of financial risk proposed.

### **Financial Risk: Generally Applicable Financial Risk Standard**

As the first part of the definition of "more than nominal risk," CMS proposes that Advanced APMs must face financial risk for losses (not just risk for business investments) and proposes a number of ways this could be structured. ASN and others had previously advocated that business risk should be factored into the concept of "nominal risk," and still supports this concept. The definition of what is "nominal" risk will vary largely by the size of a given practice; for instance, for a practice of three physicians, the proposed financial risk levels could go well beyond any interpretation of the word "nominal," and constitute a prohibitive barrier to Advanced APM participation.

The process of practice transformation required to become a successful APM involves a significant financial commitment; clinicians will need to invest in new staff and new technologies, and dedicate resources to altering care delivery processes. While these costs are more feasibly borne by some of the larger health systems and other entities (such as certain dialysis providers), independent physician practices—even moderately large practices—will be challenged to accommodate these additional expenses. A requirement for substantial financial risk for losses for Advanced APMs, layered on top of this business risk, will likely limit physician-driven participation and slow achievement of the goals of MACRA.

Furthermore, there are long-term implications of this proposal for the diversity of the number and sizes of physician practices. CMS states that it anticipates that "more and more practices" will meet these criteria over time, but it is unclear how the average practice could change to bear the risk proposed in this rule to become an Advanced APM. ASN recommends that CMS allow some APMs to "count" start-up infrastructure costs in risk level definition—and observes that this approach will permit more types of APMs to be implemented, furthering the practice and care delivery transformation goals of MACRA.

### **Financial Risk: Nominal Amount Standard**

As the second part of the definition of "more than nominal risk," CMS outlines the three proposed components of "the nominal amount standard": Minimum Loss Risk not greater than 4%; Marginal risk at least 30%; Total risk not less than 4% of total expected expenditures. ASN

recognizes that CMS believes “that statute supports a financial risk criterion that should be met only by those APMs that are most focused on challenging organizations, physicians, and practitioners to assume financial risk and provide high-value care.” This interpretation of MACRA is reasonable and ASN agrees that these are important goals, however, the society is concerned that CMS’s proposal regarding the nominal amount standard is more aggressive than necessary, and more than MACRA requires.

ASN believes that there is inherent value in creating pathways for physician-based, physician-focused models (and appreciates that MACRA calls for establishment of PFPMs) to succeed in the future landscape of healthcare delivery. Preserving the diversity of practice types and sizes is an important element in ensuring patient choice and the integrity of the patient-physician relationship. The transition out of MIPS should indeed challenge providers, but it must also be achievable. But in order to achieve this goal, CMS must establish more feasible expectations for physicians—particularly for specialists such as nephrologists.

As discussed elsewhere, people with kidney disease are among the most complex and costly patients. Assuming risk for a significant portion of excess expenditures for a population of kidney patients would be very demanding, and likely infeasible for even the largest nephrology practices in the country. While ASN recognizes that no nephrologist-focused Advanced APMs currently exist, the society believes CMS should create an environment in which such nephrologist-focused Advanced APM one day could. Nephrology care can help reduce costs and improve patient health in important ways. For example, nephrology care in patients with advanced CKD not yet on dialysis improves the likelihood that patients will receive a kidney transplant or choose less costly dialysis modalities (such as peritoneal dialysis). Great access to nephrologist care in patients receiving dialysis reduces the likelihood of hospitalizations. However, it is precisely because nephrology care can have such a significant effect on overall health expenditures, most nephrology practices interested in forming an Advanced APM will be unable to assume a potentially onerous risk for excess care costs. Here, ASN recommends several alternative options for CMS’s consideration.

- Limiting risk on using revenues received by a practice as a metric instead of total expenditures for patients (at least in some models).
- Not requiring payments back to CMS if the APM entity falls short of its anticipated revenues, as calculated by the physicians, for at least the first 2 years. Simply not receiving a bonus may be sufficient incentive for improving the ability to calculate risk, as physicians learn how to work within this new paradigm.
- Allowing certain APMs to operate for a pre-specified period of time as one-sided risk (long enough to test whether a new care delivery model is promising in terms of cost and outcomes) but with the expectation that it would transition into two-sided risk if it were to be expanded/extended.

ASN understands that CMS cannot influence the PTAC. Recognizing that new models will be coming out of the PTAC are by definition physician-focused and cannot assume the same level of risk as many of the entities that currently exist and count as Advanced APMs, ASN recommends that CMS consider a “middle ground” level of risk for PFPMs in terms of the criteria for Advanced APM status. The levels of risk proposed for Medical Home Models may be more appropriate for PFPMs and could serve as a model.

### **Comprehensive ESRD Care (CEC) Initiative and other kidney care models**

Since its establishment in 2014 as the first condition-specific model in the CMMI portfolio, the Comprehensive ESRD Care (CEC) Initiative, the Initiative offers a number of important care

delivery learning opportunities for the kidney community. While not every aspect of a care delivery model ASN supports is included in the CEC Initiative (for example, transplantation and upstream CKD care are not included), ASN is supportive of the initiative and has appreciated the opportunity to provide input to CMMI since its inception.

The society is pleased that the second round of applications has been announced and commends CMMI for implementing some important modifications to the model. In particular, ASN is pleased that CMMI is establishing the two-sided risk track for non-LDO providers. The society believes that this new two-sided risk track for non-LDO providers—which calls on the participants to assume downside risk—should count as an Advanced APM. By creating options more options for various provider types to enter into Advanced APM models, CMS increases opportunities for physicians to participate and potentially qualify as ECs—as well as contributes to diversity in the dialysis provider market, thereby facilitating patient choice.

ASN also highlights several other positive alterations to the model—such as no longer counting patients who receive zero dialysis treatments at an ESCO clinic in a performance year as a beneficiary, and permitting markets to consist of three core-based statistical areas (CBSAs), which can be connected by rural areas. These changes strengthen the model and will, ASN hopes, facilitate the participation of more providers and nephrology practices.

While supportive of the CEC Initiative, ASN also highlights that it involves only one facet of the scope of nephrology (dialysis). ASN believes that CMS and CMMI should also test other models—including, as discussed elsewhere in this comment letter physician-focused models—that provide care to patients with kidney disease throughout the continuum of kidney disease, from CKD, including but not limited to those treated with dialysis, transplantation, and conservative care.

### **Financial Risk: Capitation**

CMS proposes to count all APMs with a full capitation risk structure as Advanced APMs. Considering that APM entities would bear the full upside and downside risk in such a model, ASN concurs with CMS that full capitation risk models deserve to count as Advanced APMs.

However, the society observes that precisely because of the level of risk in a full capitation model, it is unlikely that many, if any, independent physician practices could assume this level of risk and remain independent. Because nephrologists care for a very vulnerable patient population with high rates of complication and mortality, full capitation would be an extremely challenging business model. Partnerships with entities with significant revenue and reserves would likely be necessary to support full capitation—and in many cases these partnerships may be beneficial arrangements that help achieve the goals of MACRA. However, ASN cautions that permitting an over-abundance of full capitation models will restrict the diversity of practice types in the future and contribute to consolidation.

The independence of the patient-physician relationship, and clinician latitude to individualize patient care, must be preserved and should be an important consideration in the design and selection of APMs. APMs that require physicians to partner with larger entities capable of bearing significant risk (such as full capitation) also potentially run the risk of creating a dynamic in which that independence and flexibility is marginalized. While ASN does not oppose establishment of full capitation APMs, it urges CMS to be cognizant of the potential implications on patient choice and physician autonomy.

### **Qualifying APM participant and QP determination**

ASN observes that the thresholds providers must meet in order to qualify as QPs (collectively) under an Advanced APM are complex. It may also be a challenge for certain specialists to help the APM entity achieve the thresholds to qualify its participants as QPs, or even partial QPs. The society urges CMS to consider more transparent, and less demanding, approaches to determining QP and partial QP eligibility. For nephrologists, who treat patients in multiple settings that may or may not be part of an APM, achieving the proposed thresholds may be particularly difficult (thereby making it harder for an APM Entity to collectively meet the thresholds).

ASN also observes that it is possible that some clinicians who participate in an APM and do a significant amount of their total patient volume or Medicare payments through that APM may be disadvantaged by other clinicians participating in the APM who care for relatively few patients through that APM. Presumably CMS has calculated the extent to which this possibility would be likely; the society would be interested in learning more details in this regard.

ASN notes that CMS has proposed, in cases where an Advanced APM has no Participant List, that “affiliated” practitioners could be considered for eligibility as a QP in an Advanced APM Entity. This proposition seems reasonable, but ASN requests further clarification regarding the definition of an “affiliated” practitioner – particularly if this definition varies by APM model. Furthermore, if APMs exist that have both Participant Lists and “affiliated” practitioners, ASN would encourage CMS to consider permitting both sets of clinicians to be eligible for QP status.

CMS states that “some eligible clinicians may participate in multiple Advanced APMs.” The Agency recommends that if “none of these Advanced APMs meet the threshold for the EC to qualify as APM-eligible, CMS would assess the EC individually, using combined information for services associated with that individual’s NPI and furnished through all such ECs’ Advanced APM Entities during the QP Performance Period.” ASN first requests that CMS provide examples in the final rule of the various APM combinations that would permit ECs to be participating in multiple APMs at the same time. Indeed, further guidance regarding the criteria or approaches to payment models that would permit ECs to participate in multiple payment models would be very helpful as specialty societies and other stakeholders begin to develop APMs and Advanced APMs in the future.

ASN also observes that, at present, only six APM models count as Advanced APMs, yet CMS is considering policies to account for a scenario in which *multiple* Advanced APMs Entities do not achieve the threshold for its clinicians to qualify as QPs. Does this consideration at this time point to the need for CMS to reconsider the thresholds for QP status eligibility?

### **Physician-Focused Payment Models**

ASN is enthusiastic regarding the inclusion of PFPs in MACRA and the forthcoming PTAC process. The society strongly supports these types of physician-led models and believes the testing and expansion of many PFPs is a crucial component of MACRA implementation. Here, ASN offers several recommendations concerning CMS’s proposals related to PFPs and illustrates one potential model. ASN encourages CMS to be broad in its selection process and create as many opportunities as possible to test models that are recommended by the PTAC.

ASN recognizes that CMS is not required by statute to test every model recommended by the PTAC, but encourages the agency to take every measure to test as many models recommended as possible. Not only does ASN interpret this as the goal of MACRA legislation, the society believes that the testing and implementation of *successful* PFPs is essential to

ensuring the diversity of the clinician and healthcare providers landscape—and ensuring patient choice. In support of this goal, ASN hopes that the PTAC will decide to accept proposals from the physician community on an “ongoing” basis, whenever possible. Achieving this goal will be a delicate balancing process for the PTAC, especially considering that it is likely to receive a significant number of proposals—some more well-designed, some less—upon opening for submissions. Ensuring that the PTAC has the support and bandwidth for it to assess not only the initial influx but also subsequent proposals will be an important goal for CMS.

CMS proposes to define a PFPM as “an APM wherein Medicare is a payer, which includes physician group, practices (PGPs) or individual physicians as APM Entities and targets the quality and costs of physician services,” and proposes to require a PFPM to target physician services. ASN strongly supports CMS’s proposal to focus the definition of a PFPM clearly and distinctly around the physician and/or physician practice. Permitting facilities or other practitioner types to participate is reasonable and could help facilitate coordinated care throughout the healthcare system. As CMS notes, it could also promote broader participation in PFPMs. ASN concurs with this recommendation, especially considering that it could increase physician leadership of APMs and Advanced APMs. However, ASN urges CMS to implement stringent safeguards to ensure that the physician(s) remain in an indisputable position of leadership in these cases—reflecting the goal of this aspect of MACRA as being “physician-focused.”

ASN appreciates that MACRA differentiates between APMs and Advanced APMs and that CMS has proposed criteria to set these two categories apart elsewhere in this proposed rule. However, as previously articulated, the society strongly encourages CMS to consider alternate—still appropriately rigorous, but alternate—definitions of financial risk for PFPMs. MACRA intends for as many models of care, over time, to become Advanced APMs. In order for PFPMs that are truly physician-focused to qualify as Advanced APMs, CMS will need to re-examine the proposed criteria; ASN strongly encourages the Agency to put forth alternate lower risk criteria for PFPMs (see previous comments) concerning their eligibility as Advanced APMs.

CMS proposes three categories that are consistent with the Administration’s strategic goals:

1. **Incentives:** A category of criteria that promote payment incentives for higher-value care, including paying for value over volume and providing resources and flexibility necessary for practitioners to deliver high-quality health care.
2. **Care Delivery Improvements:** A category of criteria that assess care delivery improvements that promote better care.
3. **Information Enhancements:** A category of criteria that address information enhancements that improve the availability of information to guide decision-making.

The proposed list of components that CMS proposes the Secretary would seek in proposals in each of the three categories include a number of important elements in achieving the Triple Aim. As articulated elsewhere in this letter, ASN concurs with CMS that it is important that models have evaluable goals for quality of care (including specific pre-specified outcomes criteria), cost, and other objectives of each PFPM. The society also strongly supports the proposed emphasis on patient choice in PFPM applications.

ASN appreciates that CMS and the PTAC will accept a considerable amount of supplemental information regarding proposed PFPMs, but will not necessarily require it for every application. The guidance concerning these factors, which CMS would find helpful and which may lead to more positive decisions to test models, are helpful to ASN and other potential submitters. ASN concurs that the three aspects of supplemental information CMS proposes to consider as

essential are, indeed, essential to evaluate potential models. In particular, the society strongly believes that any model tested must specify up front the anticipated size and scope in terms of number of eligible beneficiaries as well as geographic scope. These parameters are important patient protections in the context of any new approach to payment models that are inherently experiments.

The society also greatly appreciates CMS's conclusion that "types of physicians and practitioners that have had the opportunity to participate in previous APMs should not be excluded from future proposals for PFPMs because current or previous APMs are not exhaustive of all possible APMs for any given specialty or issue...so long as the proposed PFFM instead aims to solve an issue in payment policy that broadens and expands the CMS APM portfolio." ASN also thanks CMS for encouraging stakeholders to propose quality measures that are specific to their proposed APM when submitting to the PTAC.

### **Nephrology Care Delivery Model**

ASN recognizes that CMS is not seeking recommendations for new APMs or other demonstrations at this time. However, the society anticipates putting forward a "comprehensive CKD PFFM," for consideration in the future and hopes the following description will help provide context to ASN's recommendations elsewhere in this letter.

A comprehensive CKD PFFM care delivery paradigm would be a broader model than the ESCO, including patients with advanced CKD, including kidney transplant recipients, coordinating transitions across kidney disease stages, and managing and slowing the progress of kidney disease and other complex chronic conditions that are common in patients with advanced kidney disease. Inclusion of transplant patients for the duration of their lives within the scope of this model would create inherent incentives to promote transplantation for the greatest number of patients possible who are candidates. Similarly, ASN envisions that a comprehensive CKD PFFM would include palliative and/or conservative care options as those become appropriate considerations.

MACRA's enactment opens the door to developing a specialized CKD care delivery model to address the unique and significant unmet needs of this patient population. More than 20 million Americans have CKD, a condition that disproportionately affects underrepresented minorities. Patients with advanced kidney diseases suffer from multiple other serious chronic co-morbidities, including diabetes, hypertension, peripheral vascular disease, and heart failure, and commonly receive care from multiple specialists. More than 50% of patients with CKD have 5 or more other co-morbid conditions, and CKD care for patients age 65 and older exceeded \$50 billion in 2013—representing 20% of all Medicare spending in this age group.

A comprehensive CKD PFFM would present a unique opportunity to provide better cost-effective, patient-centered care that is not possible under the current delivery system, which silos ESRD care (dialysis) from pre-ESRD care and from non-dialysis care options for ESRD. Such a pilot model would target a kidney patient population "upstream" to people with CKD and follow them through end-of-life care. Spearheading the care coordination efforts, a nephrologist or nephrology practice would serve as the care leader for a population of patients from the time of their diagnosis of advanced CKD and would assume responsibility for their care—in coordination or partnership with other providers, including other physicians such as cardiologists, endocrinologists, and palliative care specialists, and entities such as transplant centers and dialysis organizations—through the transition periods of dialysis initiation, transplantation or end-of-life care.

As noted, nephrologists are specifically trained to manage patients with multiple co-morbid conditions and, in a comprehensive CKD PFFM the nephrologist and nephrology practice would assume primary responsibility of managing related comorbidities and coordinating patients' access to the multitude of other specialists needed to manage their complex conditions—with an option to form partnerships with other providers as appropriate. Effective management of co-morbid conditions is especially important for patients with earlier stages of CKD, during which proper care coordination by a nephrologist can help slow the progression of kidney disease towards ESRD, reduce provision of unsafe medications to CKD patients for whom many medications either require dose reduction or should be avoided, and help prevent the worsening of co-morbidities that are caused or exacerbated by kidney diseases, such as hypertension and heart disease.

Public accountability for quality and cost of services delivered, and shared goals across all sites of care included in the model would contribute to more patient-centered, cost-efficient care for those with the complexity of illness associated with advanced CKD. As patients progress towards kidney failure, a “comprehensive CKD care delivery model” would incentivize care coordination that improves outcomes and reduce costs, including:

- Facilitating timely, optimal preparation and education for the preferred forms of kidney replacement therapy, including all aspects and options of kidney transplantation, exposure to home therapy modalities, and vascular access planning and procedures.
- Focusing on slowing the progression of kidney disease, including patient education and incorporation of various innovative methods of disease-monitoring to enhance self-care. Eliminating the fragmentation that often characterizes the transitions of care from CKD to dialysis to transplantation.
- Allowing for thorough discussions of goals of care with patients and their families and allowing transitions to conservative and/or palliative care for those individuals who decline renal replacement therapies.

Again, thank you for the opportunity to comment on this proposed rule. ASN appreciates CMS's commitment to a transparent rulemaking process and the Agency's efforts to engage the society and other stakeholders in MACRA implementation. ASN would be pleased to discuss these comments with CMS if it would be helpful and stands ready to assist in any way; please contact ASN Associate Director of Policy and Government Affairs Rachel Meyer at (202) 640-4659 or at [rmeyer@asn-online.org](mailto:rmeyer@asn-online.org).

Sincerely,



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