

June 6, 2011

Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1345-P: Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations

Dear Dr. Berwick:

On behalf of our 12,000 physicians and scientists, the American Society of Nephrology (ASN) appreciates the opportunity to provide comments on Accountable Care Organizations (ACOs) and the Medicare Shared Savings Program. ASN is a not-for-profit organization dedicated to promoting excellence in the care of patients with kidney disease. Foremost among ASN's concerns is the preserving equitable patient access to optimal quality kidney care throughout the continuum of chronic kidney disease (CKD). For simplicity, throughout this letter, we will refer to individuals with stages 1-5 CKD not receiving kidney replacement therapy (e.g., dialysis or a transplant) as "CKD patients", end-stage renal disease (ESRD) patients receiving hemodialysis or peritoneal dialysis as "dialysis patients" and ESRD patients with a functioning kidney transplant as "transplant patients."

ASN applauds CMS' goals of elevating the quality of care and managing costs, and believes ACOs and other shared savings programs present enormous opportunity for certain patient populations. More than 26 million Americans have kidney disease, and this patient population stands to benefit from successful health care delivery reforms. However, it is crucial that CMS recognize the unique needs and significant diversity of the vulnerable kidney patient population as CMS develops the ACO program. Specifically, CKD, dialysis, and transplant patients have unique needs and vulnerabilities distinct from the general patient population and from each other. CMS must consider these differences to prevent any unintended consequences related to the quality and availability of CKD, dialysis, and transplant patients' care.

ASN believes that there are many opportunities for patients to benefit, but ACO regulations must allow for patient-centered, individualized care and for preservation of the patient-physician relationship. For multiple reasons, ACOs, as described in the proposed rule, are not well-positioned to appropriately care for patients receiving dialysis or patients with a recent kidney transplant. These patients should not be attributed to ACOs. The remainder of this letter details the rationale behind excluding dialysis and certain transplant patients from the ACO model and reviews several other major issues pertinent to the CKD population.

I. Many key ACO care processes are already routinely undertaken in dialysis units in an ESRD-specific format and setting, as implemented by the Medicare ESRD Program.

In the proposed rule, CMS recommends a number of approaches to improve the quality and reduce the cost of patient care; these include promoting evidence-based medicine best practices, patient engagement and surveying, reporting on cost and quality measures, coordination of care, and individualized care plans. ASN agrees in principle that these are all worthy actions. However, for dialysis patients, ASN respectfully submits that very few of the proposed measures for ACOs (Table 1 in the proposed rule) are valid in dialysis patients. Those few measures that are relevant and applicable to

patients on dialysis have already been implemented by CMS within the context of the Medicare ESRD Program through the Conditions for Coverage. Within dialysis units, processes are specifically designed for the unique population of dialysis patients. Each dialysis unit adheres to strict regulations including, but not limited to, data collection and reporting to CMS (and ultimately to the public via the Dialysis Facility Compare website), development of individualized care plans, and performance of patient satisfaction surveys. Currently, dialysis units submit monthly patient data for quality measures to CMS, and reporting requirements will substantially increase with the implementation of CROWNWeb.

ASN is concerned that aligning the complex existing dialysis care system with a primary care oriented ACO system that relies on metrics and reporting designed to address the needs of the general population would be an extraordinarily complex task for dialysis units, the ACO, and nephrologists without adding value to individual kidney patients' care. Redundant reporting and/or competing quality goals will lead to poor care coordination and inappropriate costly care for these complex patients. While seamless transitions of care and data sharing between providers are essential components to care coordination and meeting the requirements for a successful ACO, **subjecting dialysis patients to multiple sets of rules and processes—of both the ACO and the dialysis unit—could have an unintended negative influence on quality of care, leading to dual processes, conflicting care mandates, duplication of resources and fragmented patient care. Given the concerns related to duplication and appropriateness of care, ASN recommends that dialysis and incident transplant patients should not be attributed to ACOs, as CMS describes ACOs in this proposed rule.**

II. Primary care providers and nephrologists may have divergent approaches to caring for dialysis, transplant and CKD patients.

The majority of most nephrologists' time is spent caring for patients on dialysis. Recent CMS efforts, via the expanded bundle and the ESRD Quality Incentive Program (QIP), have specifically focused on controlling costs and maintaining quality within this venue by attributing much of the cost risks (and therefore treatment decisions) to the dialysis provider. These recent efforts are not finished products. CMS is actively working with the dialysis community to expand the list of quality indicators specifically applicable to the dialysis population. If dialysis patients were assigned to an ACO it is likely that their PCP would be responsible for a large part of their care, including balancing cost controls with ACO-mandated metrics. ASN is concerned that conflicts will arise between the nephrologist and the PCP regarding the most appropriate and/or cost-effective approach to medical care for these vulnerable patients. Dialysis is a costly treatment, and ASN is concerned that ACO providers could be perversely incentivized to reduce the costs of care in a manner that is not beneficial to dialysis patients or that does not correspond with a patient's individual wishes. For instance, it could potentially be in an ACO's best financial interest to encourage a late-stage CKD patient to select the most inexpensive dialysis modality rather than encourage home hemodialysis or incur the short-term costs of pre-emptive transplantation.

Similarly, patients who have recently received a kidney transplant or who are preparing to receive a kidney transplant also typically receive the majority of their healthcare from a nephrologist. Like patients on dialysis, transplant patients' needs are complex and distinct from the needs of the general patient population. Providing the newly transplanted patient providing safe, quality care requires specialty treatment, and ready access to the transplant multidisciplinary team will prevent complications and escalating cost of care. Furthermore, it is unclear how or whether an ACO will care for and handle the costs associated with organ donors if it is responsible for the transplant recipient, or if a beneficiary assigned to an ACO donates an organ.

Given these concerns, ASN also believes that there is a strong likelihood that ACOs will not want to assume the responsibility for patients on dialysis or at a high risk for initiating dialysis or receiving a kidney transplant. This may have a negative affect on kidney patients' access to the most appropriate care—be it dialysis or transplantation—especially in regions with just one ACO, an ACO with the minimal number of beneficiaries or with nominal provider diversity. **ASN urges CMS to ensure that patient access to, and quality of, dialysis care and transplantation options are not compromised as a result of the ACO program. Consequently, ASN feels dialysis and incident transplant patients should not be included as ACO beneficiaries.**

III. Many of the evidence-based measures, including the 65 proposed measures in the ACO document, recommended for the general population are not appropriate for dialysis, recent transplant or CKD patients.

The proposed rule describes that ACOs must “define processes to promote evidence-based medicine (EBM).” ASN strongly supports using the highest quality of scientifically validated data available to inform patient care but is deeply concerned that evidence-based measures appropriate to the general medical population cannot be generalized to the kidney disease population for the reasons detailed below. In some cases EBM may be inappropriate and even harmful for dialysis and transplant patient populations. ASN also has concerns about the availability of data supporting evidence based and consensus best practices regarding CKD patients. Accordingly, we have serious reservations about incentivizing the broad potential application of many of these measures to kidney disease patients to enable the ACO to meet the standards necessary to be eligible for shared savings.

EBM recommendations are largely extrapolated from general population studies—data sources that have routinely excluded advanced CKD, dialysis and transplant patients. Patients with kidney disease are different from the general patient population and, consequently, many EBM guidelines that are appropriate for the general population are not appropriate for patients with kidney disease. As an emblematic example of the difference between dialysis patients and the general patient population, two large, well-conducted randomized studies showed no benefit to statin use for primary or secondary prevention of cardiovascular and mortality outcomes, despite being conducted in high-risk, often diabetic patients. For these patients, prescribing statins would actually increase costs with no measurable patient or societal benefit. ACO regulations must preserve physicians’ flexibility to depart from EBM recommendations when the evidence does not apply to their patient, due to that patient’s age, chronic disease state, or other unique characteristics—and when current recommendations for the general population may prove harmful to the kidney disease patient population. As another example, the dialysis procedure directly affects systemic blood pressure, and targeting specific blood pressure guidelines pre-dialysis has the potential to cause substantial and potentially harmful drops during dialysis.

Additionally, many screening recommendations may not be appropriate for kidney patients. Given that kidney patients’ life expectancy is lower than the general population, and may be lower than the survival of patients with the diseases being screened for, many screening tests recommended for the general population are not appropriate in the management of these patients, particularly dialysis patients. In fact, for some screening tests, there may be an increased number of false positive results. This is notable for mammograms and reflects the high prevalence of benign breast calcifications in patients with late stage kidney disease and kidney failure. Negotiating these and other issues related specifically to dialysis care and dialysis metrics is an enormous undertaking. CMS is currently investing other resources in this issue through ESRD Technical Expert Panels that are specifically tasked to design appropriate metrics for dialysis care.

Furthermore, EBM guidelines may not be appropriate for patients with kidney transplants. For example, nephrologists often do not prescribe ACE inhibitors or ARBs directly after transplant, and it could be dangerous to start prescribing these in inappropriate circumstances just to achieve quality goals. Transplant patients often have a long list of medications pertaining to their transplant, particularly in the initial period following transplantation. Concerns of polypharmacy and medication interactions with their immunosuppressants and prophylactic antibiotics are legitimate. Many transplant patients may carry a diagnosis of heart failure from when they were on dialysis, but there is often regression of the left ventricular hypertrophy after transplant, post-transplant patients may no longer have the same degree of heart failure. Therefore they would not be expected to abide by heart failure guidelines.

In the non-ESRD CKD population there are also many concerns related to EBM guidelines for the general population. These concerns include possible risks of initiation of an ACE or ARB in a late-stage CKD patient with congestive heart failure or coronary artery disease, the aggressive use of statins in CKD patients (which, for example, are contraindicated in individuals with advanced CKD receiving fibrates), and the treatment of osteoporosis in patients with severe CKD in whom bisphosphonates are contraindicated and may be associated with significant harm. Finally, some patients with late stage CKD prefer a palliative care model instead of dialysis, leading to very different overall health goals and needs.

Applying the same quality measures and standards that are appropriate for the general population to dialysis patients—a vulnerable, chronic disease population with fundamentally different care needs—is clinically inappropriate. ASN is concerned that CMS does not provide any indication that the quality measures might apply differently to dialysis or transplant patients. This omission is problematic, as it could create perverse incentives for an ACO to provide care appropriate only for the general population to these patients in order to meet the standards necessary to be eligible for shared savings. **ASN urges CMS to account for the complexity, vulnerability and unique needs of CKD, dialysis, and transplant patients to ensure that ACOs do no harm, specifically exempting dialysis and recent kidney transplant recipients from attribution to an ACO. For CKD patients, as discussed below, ASN welcomes the opportunity to work with CMS to further enhance the proposed ACO program.**

IV. Many kidney disease patients receive the plurality of their care, including primary care, from a nephrologist.

CMS proposes to assign beneficiaries to an ACO based on the PCP from whom they receive a plurality (exact percent unspecified) of their primary care services. ASN notes that many nephrologists serve as primary care providers (PCPs) for their kidney patients, particularly those in late-stage CKD, those maintained on dialysis, and those who have received a transplant. For instance, nephrologists and members of the multidisciplinary nephrology care teams commonly see their dialysis patients thrice-weekly and are the most appropriate providers to determine when or if to administer screenings, routine tests, or various antibiotics depending on a patient's specific condition. It is essential that this patient-nephrologist-nephrology multidisciplinary care team relationship be preserved to maintain the highest quality of care for kidney patients. As such, **ASN suggests that dialysis patients and recent transplant recipients, populations who often receive the plurality of their care from a nephrologist, should not be attributed to an ACO. This would permit patients with earlier stages of kidney to remain in the ACO and benefit from the care processes it facilitates, but, as indicated by their disease progression, eventually allow them to receive the specialized care they need—be it dialysis or transplantation—without affecting the ACO's overall performance.**

V. ACOs may offer significant benefits for CKD patients with some key modifications.

The care of patients with CKD, especially those with more advanced CKD, is extremely complex and requires close, multidisciplinary collaboration between the patient's PCP and nephrologist as well as with other physician and non-physician providers to limit complications of their disease, including progression to kidney failure. Patients with CKD, particularly late-stage CKD, could benefit substantially from ACOs' focus on improving processes of care and overall quality. The following serves to illustrate some of the complexity of care of patients with CKD; it must be kept in mind, however, that CKD patient care must be very individualized and patient-centric. An ACO model must allow for this in order to maintain high-quality care for patients with CKD. Percent of normal kidney function is roughly equal to the percent reduction in estimated glomerular filtration rate (eGFR).

- A. **CKD with kidney function at a level of 30-50% of normal kidney function:** Outpatient care largely conducted by a PCP, with consultative care/co-management with nephrologist, diabetologist, cardiologist, and others as indicated. The nephrologist's role is largely focused on blood pressure control and limitation of CKD progression. For rapidly progressing kidney disease, nephrologist involvement may be more prominent.
- B. **CKD with kidney function at a level of 20-30% of normal kidney function:** As above, the role of nephrologist in management of CKD and its complications increases: blood pressure control, fluid overload, CKD progression, bone and mineral metabolism disorders, acidosis, anemia; avoidance of nephrotoxic kidney injury and attention to drug dosing impact of declining kidney function; dietary assessment and counseling; discussion of dialysis and kidney transplant options, including vascular access planning if hemodialysis is selected as the modality of choice. As hospitalization becomes increasingly frequent in this patient population, the nephrologist may be increasingly involved in patient care and oversight of transitions between ambulatory and in-patient settings, particularly given the industry trend of increasing inpatient care provided by hospitalists rather than the outpatient PCP.

- C. **CKD with kidney function at a level of 10-20% of normal kidney function:** As above, there is a further increase in the role of the nephrologist in overall patient care management in both ambulatory and inpatient setting as complications of CKD progress and become more severe. Referral for kidney transplant evaluation if appropriate and coordination with transplant center (nephrologists, transplant surgeons, social workers, nurses, cardiologists, diagnostic imaging, etc.) for evaluation of patient and potential living donor candidates occurs. This is also often the time for placement of dialysis access—an arteriovenous fistula or graft for hemodialysis or a peritoneal dialysis catheter for peritoneal dialysis. For many patients with this degree of kidney dysfunction, kidney transplantation before initiation of any form of dialysis is the preferred management plan requiring careful coordination between nephrologist and transplant team. Some patients with this degree of kidney dysfunction will develop symptoms of kidney failure and have metabolic or other CKD complications that necessitate initiation of dialysis.
- D. **CKD with kidney function at a level at or below 10% of normal kidney function:** As above, at this level of kidney dysfunction, if the patient has not already started dialysis he or she will typically initiate dialysis at this time unless there is a specific contraindication due to development of symptoms of kidney failure and progressive worsening of metabolic and other complications of CKD, including worsening nutritional status, anemia, acidosis, volume overload, etc. If access for dialysis has not been placed previously, it must be placed at this time—and at this time is more commonly a hemodialysis catheter initially. At this level of kidney dysfunction both before and after dialysis has been started, the nephrologist typically assumes the majority of patient care from the PCP and coordinates care with other care providers and dialysis facilities. An increasing frequency and length of hospitalization is common at this advanced stage of kidney disease; as noted above this increasingly involves the nephrologist rather than PCP in the overall care of the patient, including transitions of care between ambulatory and inpatient settings.

Given the complexity of patients with CKD, ACOs could be particularly beneficial for the patient population. Although processes that an ACO would facilitate—including electronic patient data collection and sharing, quality monitoring, individualized care plans—are prevalent in dialysis units, they are not currently widely in place for patients with CKD. Care coordination, as described on page 19547 of the proposed rule, and individualized care plans, as described on page 19551, may lead to better outcomes and more patient-centered care for CKD patients. These types of efforts could be immensely beneficial for late-stage CKD patients in particular due to the multidisciplinary nature of their care. So long as the care processes and quality standards ACOs select are appropriate for CKD patients' unique health status, ASN strongly supports these efforts for CKD patients within the context of ACOs.

For instance, vascular access planning could be streamlined in an ACO model through improved and timely communication between PCPs and specialists, as well as through incentives for vascular access to be placed prior to the start of dialysis when appropriate. Appropriate incentives could also increase communications among the nephrologist, the patient, and the PCP regarding individualizing the appropriate ESRD modality, or the decision not to start dialysis, for each patient. CKD stage 4 patients often have multiple comorbidities, and ACOs could facilitate a coordinated care plan between the PCP and multiple specialists. In addition, having the care coordination provided by the ACOs either as outpatients or transitioning from hospitalization back to the outpatient setting could improve the care of these patients.

To facilitate detection and appropriate care of patients with CKD, ASN recommends that CMS consider adding a measure of CKD care processes to the mandated quality measures. A screening measure, such as referrals for urinary albumin screening for patients with hypertension or heart disease, should also be added to the quality measures to improve the early detection of CKD and initiate early treatment to delay or prevent progression of disease and complications related to decreased kidney function. ASN would be pleased to work with CMS to develop recommendations that ACOs could use to identify when it is appropriate to screen patients for kidney disease.

Besides the potential benefits, the potential risks for CKD patients in an ACO must also be considered. One major concern is the establishment of either hemodialysis access or a kidney replacement therapy plan that does not require vascular access (peritoneal dialysis or pre-emptive transplantation). EBM guidelines have clearly established the importance of initiating dialysis with a vascular access other than a central venous catheter, which has the highest associated cost and mortality compared to other dialysis access. Unfortunately, over 80% of patients in the US currently initiate dialysis using a central venous catheter primarily because of lack of appropriate pre-ESRD care. Coordinated initiation of kidney replacement therapy with permanent access in place is associated with substantially reduced costs and improved patient outcomes. CKD patient education—a recently added benefit in the ESRD Program—is a critical component to facilitate a smooth transition to kidney replacement therapy that can lead to improved patient outcomes downstream.

Thus far, we have stressed that dialysis patients should be excluded from assignment to ACOs. This raises the concern that there may arise a perverse incentive for ACOs not to establish vascular access (or conduct other important steps in preparation for dialysis) in these patients at the appropriate time, in an attempt to avoid the cost of that care while they are part of the ACO. A solution to this is to establish timely creation of a dialysis access as a quality measure for patients with late stage CKD, therefore incentivizing ACOs to establish a dialysis access in their patients. (In some minority of patients the alternative will be the implementation of a dialysis plan that does not require vascular access: peritoneal dialysis, preemptive transplant or foregoing dialysis altogether for palliation.)

In general, ASN believes that there are many opportunities for CKD patients to benefit from assignment to an ACO. Yet regulations must allow for patient-centered, individualized care within the ACO model. For any given level of kidney function, the clinical approach will be very different depending on life expectancy (for example, an elderly patient with CKD and other comorbid medical conditions may be more likely to die before kidney failure while a younger patient is more likely to reach kidney failure than die). Please refer to Addendum 1, a description of multidisciplinary CKD care as kidney function declines, which illustrates the complexity of CKD patient care that may be faced by ACOs. **To assist ACO providers in implementing high value best practices to delay or prevent progression of kidney disease and appropriately manage CKD patients, ASN is prepared to partner with CMS to define best practice recommendations for these complex patients.**

VI. Appropriate risk-adjustment is imperative

CMS states on page 168 that: “To the extent practicable and appropriate, these outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.” ASN strongly supports risk-adjustment of these measures, but is concerned that scant information on the methodology that will be used and the conditions for which CMS will risk-adjust is included in the proposed rule. Consequently, ASN has reservations about whether adequate risk-adjustment will occur under the ACO program. Without comprehensive risk-adjustment for certain patient factors, including medical co-morbidities, the potential arises for creation of the false perception that certain ACOs—such as those with a relatively sick patient population—are not providing high-quality care. Many patient conditions, including late-stage CKD, affect the type and cost of care that is provided to them. An accurate risk-adjustment of the quality data will more accurately portray the quality of care offered in an ACO and prevent penalizing facilities that serve the most difficult patient populations.

ASN also notes that the Medicare ESRD Program recently implemented a case-mix adjustment system; the ACO Program might derive some lessons from this prior experience, both successes and challenges, many of which have yet to be identified. **ASN would be pleased to assist CMS in developing a risk-adjustment model for the ACO program that accounts for kidney disease and its associated conditions, and anticipates further clarification from the agency on this issue in the future.**

VII. Experience of care surveys yields valuable information, but the results of these surveys should not dictate whether or not an ACO is eligible to receive shared savings.

Surveying patients about their experiences of care, as described on page 87, is a vital aspect of quality and service improvement for all care providers. For example, dialysis providers have extensive experience with patient experience surveys and do act upon relevant trends. However, ASN wishes to

note that many factors—not all of which are related to the quality or timeliness of care—can influence what patients report on surveys. For instance, a patient may want an antibiotic even if he or she has a virus that would not be treated by an antibiotic. If the provider refuses to prescribe an antibiotic on those grounds, the patient may indicate dissatisfaction with their care on a survey—even though the care provided was appropriate. Although patient perceptions should not in any way be devalued, they are not necessarily reflective of the quality and safety of care administered. Including patient satisfaction responses in the criteria that determines eligibility for shared savings could create a perverse incentive for providers to administer medically unnecessary care that is desired by patients. As such, **ASN recommends that CMS mandate that ACOs must survey patients to be eligible for shared savings, but that the results of the survey not be taken into account in determining whether or not they are eligible for shared savings.**

Conclusions

ASN supports CMS' efforts to improve the coordination and quality of patient care, and to reduce the overall cost of care. With some key modifications and clarifications, ACOs may offer great benefit to certain patient populations. However, ASN emphasizes that:

- Dialysis patients and recent transplant recipients should not be attributed to an ACO
- Because patients with CKD have care needs that are complex and divergent from those of the general patient population, they require different, individualized care plans as well as ready access to care from specialists.
- ASN welcomes the opportunity to work with CMS to define:
 - Best care processes for CKD patients within the context of an ACO
 - Additional screening for kidney disease in high risk populations
 - Criteria for determining what constitutes a “recent” transplant recipient versus a recipient who has been living stably and could potentially benefit from attribution to an ACO

ASN also strongly encourages CMS to prioritize preservation of equitable patient access and patient choice, as well as the integrity of the patient-physician relationship, as it launches the ACO program. As CMS adjusts or expands the ACO and other shared savings programs, CMS may wish to explore the patient-centered medical home (PCMH) model, which could offer benefits to kidney patients in particular. ASN would be pleased to serve as a resource to help CMS assess the effects of ACOs on the kidney patient population or to offer any additional guidance that would be of assistance.

On behalf of ASN, thank you for your willingness to consider these comments about ACOs and shared savings programs at this time. ASN hopes that the principles and recommendations put forth in this letter will prove helpful and would be pleased to discuss this letter in more detail. Again, thank you for your time and consideration. To discuss ASN's comments, please contact ASN director of policy and public affairs, Paul C. Smedberg, at (202) 640-4656 or at psmedberg@asn-online.org.

Sincerely,



Joseph V. Bonventre, MD, PhD, FASN
President, American Society of Nephrology