ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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December 3, 2010

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: Medicare Program; Request for Information Regarding Accountable Care Organizations and the Medicare Shared Savings Program; 75 *Fed. Reg. 70,165* (November 17, 2010); CMS-1345-NC.

Dear Dr. Berwick:

On behalf of our 11,000 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 preservation of equitable patient access to optimal quality kidney care throughout the continuum of chronic kidney disease (CKD) and end-stage renal disease (ESRD).

ASN applauds CMS' goals of elevating the quality of care and managing costs, and believes ACOs and other shared savings programs present enormous opportunity. The society agrees that providing coordinated care can lead to savings, but must be grounded in scientific evidence. With more than 26 million Americans affected by kidney disease, this patient population stands to benefit from successful health care delivery reforms. As such, it will be important for CMS to bear in mind the unique needs and significant variance of this vulnerable patient population as it moves ahead in conceptualizing ACO models.

Preservation of the patient-physician relationship is of paramount concern for the CKD and ESRD populations. Many nephrologists serve as primary care providers (PCPs) for their kidney patients, particularly those in late-stage CKD and with ESRD, be they receiving dialysis or transplant recipients. This reality should not be overlooked as the Agency structures ACOs.

1. **What policies or standards should we consider adopting to ensure that groups of solo and small practice providers have the opportunity to actively participate in the Medicare Shared Savings Program and the ACO models tested by CMMI?**

Given that nephrologists already often serve in a PCP role for kidney patients, it is likely that some will want to participate in an ACO. Due to the complexity and costliness of kidney—and particularly dialysis—care, it is also likely that cost-savings could be derived from greater care coordination, including in the context of an ACO. Improving the transition of care for patients with late-stage CKD care to dialysis could potentially could lead to better outcomes and more patient-centered care. Consequently, nephrologists participating in ACOs would likely have interest in caring for each of these patient populations. ESRD is a relatively straightforward condition to diagnose and thus, is potentially feasible to form the basis of a condition-based specialty ACO.

However, certain practical and market-related issues may complicate nephrologists' participation in ACOs. The largest nephrology practices in the country rarely treat more than 1,500 to 2,000 patients—

and practices of this size are rare. Accordingly, it would be difficult for these physicians to form the basis of an ACO.

Preservation of patient choice in where to obtain dialysis is important to ensure equitable access to quality care and to preserve individual freedoms for a patient population whose autonomy is severely limited due to their chronic illness. In the current national environment for dialysis care, two dialysis organizations provide services to more than 60 percent of all patients. An ACO for CKD and ESRD could result in the unintended consequence of increasing consolidation, thereby limiting patient choice.

Thus, consideration of smaller patient bases may be reasonable for an ACO based on ESRD and CKD, as this would alleviate concerns regarding consolidation particularly considering the high complexity and cost of such people's care. Should the Agency permit a nephrology ACO, ASN believes that such an ACO should:

- Provide high-level care specifically for the vulnerable patients with ESRD and advanced CKD
- Maintain patient choice
- Assure the patient-physician relationship
- Provide cost-efficient, patient-centered care based on best available scientific information

Additionally, in light of the sizeable nephrology patient population, CMS should consider mechanisms by which nephrologists and nephrology practices can participate in PCP-based ACOs. Nephrologists could play a role similar to that of the "neighbor" described in the Patient-Centered Medical Home (PCMH) model.

2. Many small practices may have limited access to capital or other resources to fund efforts from which "shared savings" could be generated. What payment models, financing mechanisms or other systems might we consider, either for the Shared Savings Program or as models under CMMI to address this issue? In addition to payment models, what other mechanisms could be created to provide access to capital?

Electronic Medical Records (EMR) will be crucial to integrating care and will predicate ACOs' ability to coordinate care and reduce costs. However, for a small practice that is not part of a larger organization, obtaining an EMR may be prohibitive, creating a barrier to participation in an ACO. CMS should explore the possibility of rebates, loan guarantees, or other forms of financial assistance to help enable smaller and independent practices participate in ACOs. Additionally, any predictions CMS can offer regarding the amount of savings ACO participants may earn if they are successful in restructuring care delivery may incentivize small practices to invest in EMR.

3. The process of attributing beneficiaries to an ACO is important to ensure that expenditures, as well as any savings achieved by the ACO, are appropriately calculated and that quality performance is accurately measured. Having a seamless attribution process will also help ACO's focus their efforts to deliver better care and promote better health. Some argue it is necessary to attribute beneficiaries before the start of a performance period, so the ACO can target care coordination strategies to those beneficiaries whose cost and quality information will be used to assess the ACO's performance; others argue the attribution should occur at the end of the performance period to ensure the ACO is held accountable for care provided to beneficiaries who are assigned to it based upon services they receive from the ACO during the performance period. How should we balance these two points of view in developing the patient attribution models for the Medicare Shared Savings Program and ACO models tested by CMMI?

As previously mentioned, many nephrologists serve as the primary care provider for patients on dialysis. This creates a potential opportunity for nephrologists to serve as the center of an ACO, with patients directly attributed to them.

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However, given the variation in individual patients' progression from CKD to ESRD as well as the multiple approaches to measuring and defining CKD stages, attributing patients to a nephrology ACO—either prospectively or retrospectively—would present significant challenges. Again, if CMS does permit nephrology ACOs, the Agency should take every effort to prevent any potential market consolidation.

Furthermore, when determining the attribution process, ASN strongly encourages CMS to bear in mind the potential to create any perverse patient selection incentives for ACOs. CMS should consider strategies to ensure that ACOs—as well as other care delivery restructuring efforts—reach a diversity of patient populations, including socioeconomically and medically disadvantaged groups.

4. How should we assess beneficiary and caregiver experience of care as part of our assessment of ACO performance?

Assessment of beneficiary experience can be accomplished via a variety of existing validated instruments, including those from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys, products from organizations including the Health Resources and Services Administration (HRSA), the RAND Corporation, and Press Ganey. ASN believes that it would be appropriate consider use of condition-specific instruments for evaluating beneficiary and caregiver experience in unique care environments, such as dialysis. For this patient population, the SF-36 is a simple quality-of-life instrument that is responsive to changes in CKD and ESRD therapy.

Besides consideration of appropriate instruments, ASN encourages CMS to work with the physician community to address questions such as the frequency of patient evaluation, role of responses in assessing ACO performance, and adjustors. *Because a large number of measurement issues are involved, ASN suggests that CMS establish a diverse, independent, stakeholder group to oversee this process.*

5. The Affordable Care Act requires us to develop patient-centeredness criteria for assessment of ACOs participating in the Medicare Shared Savings Program. What aspects of patient-centeredness are particularly important for us to consider and how should we evaluate them?

Unlike assessing beneficiary and caregiver experience, instruments that attempt to assess patient-centeredness will likely need to be context-specific. For instance, by illness (e,g. acute vs. chronic), disease (e.g. asthma, diabetes, ESRD, congestive heart failure, cancer, etc], location [ER, inpatient, outpatient, etc) and other similar variations. This raises significant measurement and oversight challenges. Nonetheless, ASN believes it may be possible to determine a simple, common, generic scale capture certain broad classes of encounters and experiences. These could include, for instance, location-based classes such as Emergency Department, inpatient, outpatient, or time-based classes such as one month, or one year. However, because these measures may ultimately be linked to financial incentives, they should be rigorously evaluated across the range of contexts and populations to which they will be applied.

Despite the challenges, ASN suggests that appropriate measures of patient-centeredness criteria for nephrology patients in an ACO could include the following:

1. Coordination of care (e.g. transition from hospital to dialysis unit or between PCP and specialist
2. Patient education and involvement in treatment plan, including but not limited to transplantation, dialysis modality, access planning, dietary counseling and end of life care
3. Use of home (self-care) or alternative dialysis therapies (e.g. home hemodialysis and peritoneal dialysis)

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6. In order for an ACO to share in savings under the Medicare Shared Savings Program, it must meet a quality performance standard determined by the Secretary. What quality measures should the Secretary use to determine performance in the Shared Savings Program?

Any quality measures that CMS selects to determine performance of ACOs or other shared savings programs should be firmly rooted in robust scientific evidence. Preferably, CMS would select measures or targets that have been prospectively demonstrated to lead to improved clinically important patient outcomes. The society is concerned that incentivizing providers to achieve performance targets that have not been validated could potentially lead to unintended consequences for patients. As such, ASN believes it is crucial for CMS to distinguish between consensus-based measures and evidence-based measures. Financially rewarding providers' behavior should be based on evidence that this behavior improves meaningful patient-centered outcomes, not just intermediate outcomes.

Risk-adjustment remains an issue in the ACO context and deserves attention as CMS develops performance standards, especially in light of recent publications indicating that the majority of the variation remains at the patient-level rather than facility-level. This is particularly crucial for the dialysis population given the death of evidence in the nephrology arena.

Due to the variation in dialysis patient compliance and characteristics, performance scores are not necessarily an accurate reflection of the quality of care providers offer at a facility. Accordingly, the society submits that public reporting of facility-level performance scores without any indication of case-mix would be problematic, as it omits vital contextual information about the significant variance in patient populations between facilities. As elaborated above, the society strongly suggests that CMS consider case-mix adjustors or other risk-adjustment measures, particularly if this data will publicly reported.

7. What additional payment models should CMS consider in addition to the model laid out in Section 1899(d), either under the authority provided in 1899(i) or the authority under the CMMI? What are the relative advantages and disadvantages of any such alternative payment models?

Ahead of implementation of the Affordable Care Act, the Medicare ESRD Program is instituting a fully-bundled payment system for dialysis care, which includes all costs related to the provision of dialysis other than physician fees on January 1, 2011. The Medicare ESRD Program will also be implementing the first-ever pay-for-performance program on January 1, 2012. CMS should look to these early experiences with payment reform to inform the design and implementation of future pilot programs, learning from the success and shortcomings in the dialysis arena. While the parallels are not likely to be direct between ESRD and other disease or conditions, the experiment in reimbursement and quality improvement programs could provide fundamental insights to other areas. Lessons from the ESRD bundled payment program may be of particular relevance if CMS chooses to explore condition-specific capitation payment models.

As CMS considers additional payment models, ASN encourages CMS prioritize preservation of equitable patient access and patient choice, as well as the integrity of the patient-physician relationship. CMS may wish to explore the PCMH model, which could provide an opportunity for nephrologists—including those in small or independent practices—to participate in shared savings programs and provide more patient-centered care for CKD and ESRD patients. CMS should closely monitor any care delivery models piloted to assess potential effects on patient access and outcomes, preferably including an independent stakeholder panel.

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Conclusions

On behalf of ASN, thank you for your willingness to consider these comments about ACOs and shared savings programs at this time. ASN believes that ACOs and similar payment and care delivery reforms offer significant potential to improve the quality of care for kidney disease patients and manage health care costs. The society appreciates the agency's openness to comments from the nephrology community at this early stage, and looks forward to working with CMS throughout the rulemaking process. The society hopes that the principles and recommendations put forth in this letter will prove helpful, 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) 416-0640 or at psmedberg@asn-online.org.

Sincerely,

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President, American Society of Nephrology