Introduction

As profound concerns regarding the continuing growth and future sustainability of the Medicare program continue unabated, efforts to ensure that the finite financial resources of the program are utilized in the most effective and cost-efficient manner possible have proliferated. The proposed model for achieving these twin goals with the most current relevance is the accountable care organization (ACO). An ACO is generally defined as an integrated payment and health care delivery model that coordinates services provided by physicians, hospitals and other specialty providers to deliver care to a defined patient population and which determines success based on quality metrics and overall cost savings. To an extent unseen with previous efforts to improve patient care and simultaneously spend Medicare funds more efficiently, the ACO concept has the blessing of the federal government via legislative mandate and regulatory promulgation.

It is important to bear in mind that the significance of the development of ACOs and ACO-like models is not just about these specific proposals themselves, but rather it is as a likely harbinger of a broader paradigm shift in healthcare delivery and reimbursement. In advocating for repeal of the sustainable growth rate (SGR) system for Medicare Part B reimbursement, the AMA and umbrella organizations for internal medicine, general surgery, cardiology and other specialties have urged Congress to: (1) repeal the SGR; (2) provide approximately 5 years of payment stability in the Medicare program; and (3) implement ‘innovative’ payment methodologies that would replace Medicare fee-for-service after 2017 (approximately). As such, the likelihood that the volume based Medicare fee-for-service (FFS) structure currently in place will look significantly different in a few years is possible if not probable with the expected evolution of the FFS model toward progressively more performance measurement and risk.

The purpose of this document is to provide nephrologists and nephrology practitioners with counsel in determining the best path forward for their particular practice or practicing arrangement as ACO and similar models are created, implemented, and refined. Specific guidance on nephrologist interactions in the ACO arena is provided prospectively in the document. Subsequently, the legislative and regulatory background for ACOs and how nephrologists may be able to interact with ACOs and similar models, including both a focus on proposals for implementing kidney-specific integrated care models and different scenarios for nephrologists participating in general ACOs, are described. While the counsel offered in this document was developed in the context of the Medicare ACO model, the
guidance may also be applicable to interacting and negotiating arrangements with private payers developing ACOs.

RPA Guidance to Nephrologists Regarding ACOs

1. Nephrologists should recognize that the development and implementation of ACOs and ACO-like models is occurring and represents what may be a permanent shift in how healthcare delivery and payment is achieved in the U.S.

2. Nephrologists are encouraged to be aware of the development of ACOs and similar models in their geographic areas, and to contact hospital administrators and other likely entities to determine what their organizations are planning and how the nephrologist can be involved in the provision of kidney patient care. Further, nephrologists should be prepared to be contacted by general ACOs to provide care to the kidney patient population specific to that ACO.

3. Nephrologists should understand that in refinements to the general ACO models proposed by CMS, how a specialist is defined for the purposes of the ACO model has evolved, based on the degree to and circumstances under which a specialist has provided primary care services to the patient. These refinements could result in the nephrologist being designated as the patient’s primary care physician and thus limited to participating in a single ACO. Nephrologists should be mindful of these issues when evaluating participation in an ACO.

4. Nephrologists should be aware that the Center for Medicare and Medicaid Innovation (CMMI) may solicit proposals allowing a kidney specific ACO-like model or renal integrated care model in early 2013.

5. Nephrologists should recognize that there may be are a range of options available for participating or not participating in an ACO, including choosing not to affiliate with an ACO and continuing to provide services and bill Medicare for fee for service services for Medicare patients attributed to the ACO, serving as a primary care physician where applicable, contracting with an ACO to provide care to kidney patients, entering into a joint venture agreement with an ACO, or becoming fully employed by an ACO.

Federal Legislative and Regulatory Foundation for ACO Development

Legislative Background
A key passage of the Affordable Care Act (ACA) was the inclusion of Section 3022, which directed the Centers for Medicare and Medicaid Services (CMS) to establish within the Medicare program a shared savings program (known as the Medicare shared savings program—MSSP) that would, in CMS’ words:

...facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce unnecessary costs. The Shared Savings Program is designed to improve beneficiary outcomes and increase value of care by:
Promoting accountability for the care of Medicare FFS beneficiaries;  
Requiring coordinated care for all services provided under Medicare FFS;  
Encouraging investment in infrastructure and redesigned care processes.

Eligible providers, hospitals, and suppliers may participate in the Shared Savings Program by creating or participating in an Accountable Care Organization, also called an ACO. Thus by legislative fiat, the ACO concept as part of the Medicare program was born in March 2010.

ACO Rulemaking Process

Proposed Rule

On March 31, 2011, CMS, the Department of Justice (DOJ), the Internal Revenue Service (IRS), the Federal Trade Commission (FTC), and the Office of Inspector General (OIG) released a series of four regulations governing the development and oversight of the ACO care delivery model mandated by the ACA of 2010. The four rules consist of: (1) the ACO rule itself, issued by CMS and addressing issues such as governance, quality and payment structure; 2) a collaborative effort by the DOJ and FTC on antitrust enforcement and ACOs; 3) a collaborative effort between CMS and the OIG on proposed waivers for Medicare ACOs from the self-referral, anti-kickback, and civil monetary penalties statutes; and 4) an IRS proposal on the tax issues emanating from development of ACOs. The scheduled implementation date for ACOs outlined in the proposed rule was January 1, 2012.

CMS noted in the proposed rule that if the providers in an ACO are able to meet quality performance benchmarks and cost savings thresholds, those providers will be eligible to receive payments for shared savings. However, the proposed ACO model also expected participating entities to share in losses as well through what was termed a two-sided risk model, in which ACOs would have to repay Medicare for losses if a portion of Medicare spending for their patients exceeded the benchmark level.

In the most noteworthy proposed rule news for nephrology and other specialties treating unique disease states, CMS did not waive the requirement that the ACO enroll patients specifically assigned to primary care physicians, and also maintained a minimum patient census of 5,000 patients for forming an ACO. The de facto impact of these requirements was that they did not allow for the establishment of disease-specific ACOs, including a kidney-specific ACO. In advance of the rulemaking, RPA and other groups in the kidney care community had advocated for the creation of a disease-specific ACO for the following reasons:

- The uniquely well-defined nature of the end-stage renal disease (ESRD) patient population;
- The integrated system of providers necessary to appropriately care for ESRD patients;
- Nephrologists and dialysis facilities have received capitated and bundled reimbursements, respectively, for the better part of several decades providing experience with payment systems likely to be used in the ACO model;
The detailed data gathering on ESRD patients provided by the United States Renal Data System (USRDS) that has been in place for over a decade;
- The nephrology community has extensive experience with the development and reporting of clinical performance measures and therefore, has as much if not more experience with having its performance measured than any other group of disease-specific providers; and,
- The successful experience of the ESRD Disease Management Demonstration Project, which in a model similar to that proposed for ACOs, utilized integrated care coordination to improve care and save money.

Despite these compelling reasons, CMS utilized a strict constructionist interpretation of the underlying legislation in developing the proposed rule. The manner in which the proposed rule was created would have made it difficult for any entity to establish itself and thrive as an ACO, due to the degree of risk that a potential ACO must assume, the minimum savings requirements established in the proposed rule, and retrospective assignment of enrollees that may make forecasting of costs challenging if not impossible. It would have been even more difficult if not impossible for a disease-specific or specialty-specific ACO to be established within the parameters described in the proposed rule. It is somewhat telling that CMS estimated in the rule that only 75-150 ACOs will form between 2012 and 2014 years, a seemingly paltry figure relative to the intense interest in ACOs that occurred after passage of the ACA.

Final Rule

On October 20, CMS released the final rule outlining its plan for the creation of ACOs. The final rule indicates that there will be two application periods for the first year of the Shared Savings Program with respective effective dates of either April 1, 2012 or July 1, 2012. While CMS' proposed rule was not received positively, the Agency took substantial steps in the final rule to address stakeholders' concerns.

The ACO final rule scaled back several of the most onerous requirements included in the proposed rule even further. Among the actions that the Agency took in the final rule are:

- Reducing the number of quality care metrics from 65 measures in 5 domains to 33 measures in 4 domains;
- Relaxing requirements regarding use of electronic health records (EHRs), including no longer having EHR use be a condition of participation;
- Providing alternative pathways for participating entities to avoid incurring payment penalties if they do not meet savings targets;
- Removing two-sided risk in year 3 from the Track 1 ACO option (the proposed rule called for Track 1 to have two years of one-sided risk followed by one year of two sided risk);
• Beginning shared savings on the first dollar for all ACOs once minimum savings rates have been achieved (the proposed rule called for sharing to begin at savings of 2%); and

• Offering physicians and rural providers access to upfront capital via an advanced payment program.

It remains to be seen whether the changes CMS made will provide sufficient incentive for eligible participants to take the plunge and either form or choose to participate in an ACO. However, the changes from the proposed rule to the final rule do represent fairly significant movement by the Agency to address concerns raised by the pool of possible stakeholder entities.

In addition to the finalized ACO program, the Center for Medicare and Medicaid Innovation (CMMI) introduced an Advanced Payment Model that will test whether-paying a portion of future shared savings from the Medicare Shared Savings Program will increase participation. The Advanced Payment Model ACO will be available to small ACOs such as small practices and rural community hospitals that do not have inpatient facilities or would not otherwise be able to form an ACO. This model will provide upfront payments to eligible entities.

CMS Selection of ACO ‘Pioneer Models’

On December 19, 2011 CMS announced that 32 organizations had been selected as ‘Pioneer’ ACOs to test the impact of using innovative payment arrangements on efforts to simultaneously enhance coordination of care and cost savings. The groups were selected for: (1) their experience in providing coordinated, patient-centered care; (2) demonstrating commitment to the ACO model by pursuing it with private payers as well; and (3) agreeing with CMS on not only the specifics of the Pioneer arrangement, but also to be part of a larger movement toward new models of care. Further information on the Pioneer ACO Initiative and a list of the 32 selected entities is available at http://innovations.cms.gov/initiatives/aco/pioneer/.

Nephrologists who practice in geographies served by one of the 32 Pioneer entities may want to consider contacting the organization to explore opportunities to provide care to that group’s participants with kidney disease. It is likely that the organization will want to contract out those services provided to kidney disease patients and may provide an opportunity for nephrologists to familiarize themselves with ACO arrangements and administration.

Nephrology-Specific Pathways for Participation

CMMI and Renal-Specific Integrated Care Models

On a parallel track with CMS’ efforts to implement an ACO care delivery model broadly, CMMI has been meeting with organizations seeking to provide disease specific care in ACO-like structures known as an integrated care models (ICMs). RPA has been participating in one of these collaborative efforts with dialysis providers to develop and implement a renal-specific ICM as an alternative to a renal specific ACO. Elements of a renal ICM would include but not be limited to:
• Patient population limited to ESRD;
• Use of a patient-centered model of care developed in collaboration with nephrologists;
• Prospective attribution (i.e., patient assignment prior to implementation);
• A requirement for health information technology (HIT) capabilities for entities with more than 500 patients;
• Use of payment models that complement, rather than replace, existing payments under original FFS Medicare (thus not affecting the monthly capitated payment—MCP—for nephrologists); and
• Quality measurement based on five domains (patient experience, preventive health, renal disease process and outcomes, coordination of care, co-morbidity management).

There are several compelling reasons why RPA believes that a renal ICM addressing the needs of the kidney patient population should be established. First, it is unlikely that the unique needs of ESRD patients will be addressed in non-kidney disease specific ACOs, and that the absence of an ICM program will expose these patients to a care delivery model lacking the unique degree of nephrology expertise that would exist in an ICM. Second, there are numerous aspects of the current kidney care delivery environment (such as a well-defined patient population, frequent and coordinated interactions between patients and their nephrologists/providers of care, substantial quality measurement and improvement activities, and use of alternative payment methodologies) that are uniquely suited to the creation of an ICM. Third, the results of the first three years of the CMS ESRD Disease Management Demonstration Project showed (1) improvement in hospitalization, mortality, and transplantation related measures; (2) improvement in patient outcomes and processes of care; (3) improvement in patient quality of life, experience, and satisfaction measures; and (4) a reduction in the overall cost of care when compared to traditional fee-for-service (FFS) expenditures.

As this guidance is being revised in November 2012 CMMI has not issued a final decision on whether to allow the development and implementation of a renal ICM, although discussions with the Agency indicate that CMMI senior staff has a favorable disposition on the concept. It is reasonable to expect that CMMI will reach a decision by the end of 2012 or in early 2013.

Models for Nephrologist Interaction with General ACOs
Nephrologists have several options for interacting, or not interacting, with general ACOs in their specific localities. These include but are not limited to: (1) not affiliating with any ACOs, and continuing to provide care to patients under the current fee-for-service structure; (2) serving as a primary care physician in an ACO structure for those patients where applicable; (3) contracting with an ACO to provide care to kidney disease patients under a pay-for-performance type of arrangement; (4) participating as a partner in a joint venture ACO entity; and (5) becoming fully employed by an ACO to provide care to their kidney disease patients.
Nephrologists Opting Not to Affiliate with an ACO

Nephrologists may choose not to participate in an ACO in their geographic area. If a suitable arrangement that fits with the nephrologist’s practice patterns and patient census is not available, the most prudent course may be to defer affiliating with an ACO. While some aspects of ACO participation are attractive, such as improved care coordination, shared savings, and the experience gained in a possible new model for healthcare delivery, nephrologists should not be rushed into a participation agreement, and should proceed with due deliberation.

Nephrologists as Primary Care Physicians

While CMS did continue its de facto prohibition of disease specific ACOs, it did take some actions that could facilitate the ability of nephrologists and other specialists to participate in an ACO. First, the final rule does indicate that CMS will recognize primary care services provided by specialists for purposes of assignment. Thus, if a nephrologist or other specialist is providing primary care to a patient as evidenced by the claims service mix submitted for that patient, and the patient is not being seen by a primary care physician (PCP), the specialist could participate in the ACO. The text by which CMS indicates this change is noted below:

Under this (step-wise) approach, beneficiaries are first assigned to ACOs on the basis of utilization of primary care services provided by primary care physicians. Those beneficiaries who are not seeing any primary care physician may be assigned to an ACO on the basis of primary care services provided by other physicians. This final policy thus allows consideration of all physician specialties in the assignment process.

While the CMS decision does allow specialists such as nephrologists to serve as the patient’s primary care physician under the limited circumstances described, this path will be difficult for most nephrologists to navigate. Further, if a nephrologist decides to serve as a PCP in an ACO, it may prohibit their ability to serve as a nephrologist in another ACO; thus, this is a decision that the nephrologist must consider carefully. Given these factors, the most likely corridor for nephrologist participation in a general ACO will likely be as an employee of the ACO or through a contractual arrangement with such an entity. Regarding the issue of nephrologists serving as primary care physicians, as noted above nephrologists should be aware that CMS' method for defining primary care physicians for the purposes of ACOs has evolved, and this could limit the ability of nephrologists to participate in multiple ACOs. RPA’s interpretation of CMS regulations in this specific area is provided below:

- A physician can only participate (formal agreement with) in one MSSP ACO if that physician is the physician providing primary care services to an assigned beneficiary based upon the stepwise physician assignment process detailed below.
- The beneficiary attribution process into an ACO is prospective based upon the previous 12 months claims experience for “primary care services”, and is subject to quarterly retrospective reconciliation for accuracy and updating. Primary care
services are defined as CPT codes 99201-99215, 99304, 99341-99350, The Welcome to Medicare Visit

- The process of assignment of a physician to a particular ACO is based upon several factors: (1) the physician must first be a provider/supplier within an ACO (a formal participation agreement wherein the physician’s practice TIN is submitted to CMS by the ACO as a participating practice), (2) “after identifying all patients that have had a primary care service with a physician who is an ACO provider/supplier in an ACO, [CMS] will employ a stepwise approach as the basic assignment methodology”. Physicians’ NPIs are used to identify them as provider/suppliers – but it is their TIN that subjects them to the exclusivity restrictions of single MSSP ACO participation (See below re: use of more than one TIN for a practice).
- “Under this stepwise approach, beneficiaries are first assigned to ACOs on the basis of utilization of primary care services” (as defined by the CPT codes above) “provided by primary care physicians” (defined as IM, geriatrics, or FP). This is step one. If the beneficiary has seen a primary care physician for at least one visit wherein one of the above CPT codes was used, the assignment process’s primary care provider identification process stops at step one. Those beneficiaries who are not seeing any primary care physician may be assigned to an ACO on the basis of primary care services provided by other physicians, including specialists (e.g. nephrologists). That is step two.
- For step one, if a beneficiary has seen more than one primary care physician during the attribution period, the one providing the plurality of primary care services (based upon allowed charges) is the one to whom that beneficiary is assigned, and thus they are assigned to that physician’s ACO.
- Step two would consider only beneficiaries who have not received any primary care services from a primary care physician either inside or outside the ACO. “Under this step a beneficiary will be assigned to an ACO only if he or she has received at least one primary care service from any physician (regardless of specialty) in the ACO during the most recent year (prospectively) or performance year (retrospectively)”. This step is again reached only if step one is not satisfied (i.e. only if there is no primary care service provided by a primary care physician). Provider/suppliers also include NPs, PAs, CNSs.
- Specialists who are identified in step two as primary care providers may only participate in a single MSSP ACO, except under a circumstance in which they utilize a unique (second or more) TIN for their participation within the ACO, as it is the provider/supplier’s practice TIN, not their individual NPI, that determines exclusivity to an MSSP ACO.
- There may be circumstances in which a nephrologist sees ESRD patients in an outpatient setting outside of the dialysis facility for reasons not covered within the scope of services of the MCP wherein CPT 99201-99215 could be used. Whereas the MCP codes do not qualify as primary care services per the MSSP ACO Final Rule, these other codes do qualify, and thus use of those codes could trigger the stepwise assignment process detailed above.
- Providing care to CKD patients of course means that CPT codes 99201-99215 will be utilized, and if these patients do not have a Primary Care Physician (PCP) who used one of these codes as described above, the nephrologist would be considered the patient's PCP as part of Step 2.
• An agreement with an MSSP ACO does not have to be a formal participation agreement i.e. wherein a practice’s TIN is utilized by the ACO and submitted to CMS as a formal participant in the ACO. It can be a contract to provide specialty services, or an informal arrangement to be available to provide services as is common presently, and with continued CPT charge submission directly to Medicare.

RPA will work with the broader organized medicine community to advocate for any necessary revisions in the regulation to preserve nephrologists’ autonomy as ACOs evolve.

**Nephrologists with an ACO Contractual Agreement**

The Final Rule permits specialists to join more than one ACO. Regardless, as nephrologists in many communities service more than one hospital or hospital system, and in many cases nephrologists from other practices also provide specialty care in those same hospitals, the competition for being the nephrologist of choice is likely to remain unchanged. However, if the ACO were to select one practice over another, perhaps based upon a demonstrated ability to provide added value to the ACO (best quality outcomes, lowest utilization/costs), one practice may stand to gain based upon such value-creation at the other’s expense.

All services provided by physicians who care for Medicare beneficiaries in a fee for service environment and attributed to the ACO will, according to the Final Rule, continue to be fee-for-service-based, with payment for such CPT codes continuing to remain the responsibility of CMS as is the case now (i.e. the payer is Medicare, not the newly formed hospital-primary care physician ACO). Unless or until such time as the ACO assumes full risk (i.e, is paid a fixed amount to provide care for the attributed population and then has the responsibility to pay the physicians for contracted services) nephrologists will remain fee for service specialists, even for patients who have been attributed to the ACO, billing Medicare for their services.

Thus, if a contract for services were to be negotiated between nephrologists and the ACO, it would more than likely be a means to participate in a portion of the shared savings potentially available to the ACO from CMS. We can envision a situation in which no nephrologist is excluded from providing services to an ACO, or one in which selected nephrologists have a contract with the ACO for participation in shared savings, and/or an agreement is reached between the ACO and the nephrologists where the nephrologists who provide the highest value are made the preferred providers, also potentially participating in shared savings.

**Nephrologists as Partners in a Joint Venture ACO Entity**

In certain geographies nephrologists may have the opportunity to become a partner in a joint venture ACO or ACO-like entity. Under such an agreement the nephrologist would have more control and a greater voice in decision making in issues such as how to achieve appropriate care coordination, quality improvement, agreements with specialists and other external parties, and logistical arrangements.
However, nephrologist partners in joint ventures would also be exposing themselves to a substantially greater level of risk if the ACO entity failed to reach quality benchmarks, savings targets, or other metrics established by either CMS or private payers.

**Nephrologists as Full-Time Employees of ACOs**

Hospitals and other organizations are developing models akin to the Physician Hospital Organizations (PHOs) that initially became popular in the 1990s, a sign of their initial preparation to move into the ACO arena. While the agreements these entities have with physicians are primarily with PCPs, specialists are also being asked to join. Among primary care physicians and cardiologists, hospital employment is becoming more common. There seem to be few circumstances where nephrologists have become fully employed by hospitals and similar entities to date, outside of existing staff model health systems. Employment by the hospital or health system may be a desirable arrangement for some nephrologists, depending on the particular circumstances of the employment agreement. However, in entering into an agreement of this nature, the nephrologist would be ceding much of their leverage and control over their working environment and pattern of practice. It is thus recommended that nephrologists consider seeking legal guidance when negotiating such arrangements.

**Summary**

It is clear that there are going to be a significant but not yet known number of hospitals/hospital systems applying to become ACOs. Some markets will have ACOs present while others will not and will instead wait to see what happens before acting in this regard. RPA advises nephrologists to stay alert to what is happening in your practice areas, contact your health system or hospital administrators about their plans and how you can help/be involved in the provision of kidney care, and provide feedback to RPA by email to rpa@renalmd.org as you gain information regarding changing care delivery models in your geographic area. RPA has been asked by CMMI to provide such feedback, and we will do so in a blinded manner as we receive it.