

Considering an Integrated Nephrology Care Delivery Model: Six Principles for Quality

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Summary

In 2012, 27 organizations will initiate participation in the Medicare Shared Savings Program as Accountable Care Organizations. This level of participation reflects the response of Centers for Medicare and Medicaid Services to criticism that the program as outlined in the proposed rule was overly burdensome, prescriptive, and too risky. Centers for Medicare and Medicaid Service made significant changes in the final rule, making the Accountable Care Organization program more attractive to these participants. However, none of these changes addressed the serious concerns raised by subspecialty societies—including the American Society of Nephrology—regarding care of patients with multiple chronic comorbidities and complex and end stage conditions. Virtually all of these concerns remain unaddressed, and consequently, Accountable Care Organizations will require guidance and partnership from the nephrology community to ensure that these patients are identified and receive the individualized care that they require. Although the final rule fell short of addressing the needs of patients with kidney disease, the Centers for Medicare and Medicaid Innovation presents an opportunity to test the potentially beneficial concepts of the Accountable Care Organization program within this patient population. The American Society of Nephrology Accountable Care Organization Task Force developed a set of principles that must be reflected in a possible pilot program or demonstration project of an integrated nephrology care delivery model. These principles include preserving a leadership role for nephrologists, encompassing care for patients with later-stage CKD and kidney transplants as well as ESRD, enabling the participation of a diversity of dialysis provider sizes and types, facilitating research, and establishing monitoring systems to identify and address preferential patient selection or changes in outcomes.

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Introduction

This year, 27 organizations will initiate participation in the Medicare Shared Savings Program as Accountable Care Organizations (ACOs). Although this number is significantly fewer than the 200 ACOs that the Centers for Medicare and Medicaid Services (CMS) projected, 27 participants could be considered robust participation given that the initial proposal was widely criticized as administratively burdensome, overly prescriptive, and offering too few rewards relative to the potential expense and financial risks—even by the institutions on which it was modeled (1,2).

CMS received more than 1,300 comments on the proposed rule released in the summer of 2011, including comments from the American Society of Nephrology (ASN). Most of this feedback was negative, but CMS responded with significant changes, and the level of interest in the program rose (3,4).

Important modifications in the final rule included creating more opportunities for providers to share in savings, relaxing the Electronic Health Records meaningful use criteria, and reducing the number of quality measures that ACOs must achieve from 65 to 33 (Table 1). The Pioneer ACO program allows start-up ACOs even more flexibility. The goals of the ACO program—to improve care coordination, deliver high-quality care

more consistently, and reduce costs to the health care system—are vital and timely. The launch of the ACO program is a milestone in the Medicare system, one that may prove pivotal to the course of health care delivery in the United States.

However, significant challenges remain for patients with major chronic diseases and their providers. None of the changes to the proposed rule address the serious questions and concerns raised by ASN regarding care of patients with multiple chronic comorbidities and complex and end stage diseases—concerns echoed by other subspecialties, such as oncology. As expected, the final rule explicitly stated that the ACO program will remain focused exclusively on the general patient population, prohibiting any specialty-specific options. Consequently, virtually all of the concerns the ASN and other specialty societies voiced regarding the proposed rule remain unaddressed on the eve of the program's launch.

ASN had cautioned that ACOs, as described in the CMS proposed rule, would not be well positioned to appropriately care for patients receiving dialysis or patients who have had a recent kidney transplant, recommending that these patient populations be excluded from attribution to an ACO. Also, ASN expressed concern that many of the proposed quality

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Table 1. Important changes between the Accountable Care Organization proposed and final rules

Aspect of ACO Program	Detailed Changes
Financial provisions	The final rule reduces financial risk and allows for all ACOs to earn savings from the first dollar saved. CMS initially proposed a rule that only ACOs that shared financial risk in the two-sided model could share in savings from the first dollar that their ACO saved Medicare. The final rule also eliminates a 25% withhold of savings for all participants.
Application and structural changes	The final rule eliminates the initial application requirement to obtain a mandatory Antitrust Agency review and instead, provides a voluntary expedited review. The requirement to undergo an Antitrust Agency review each time an ACO adds a provider or supplier was also eliminated.
Eligible entities	The proposed rule listed the four groups outlined in the Affordable Care Act and critical access hospitals paid through Method II as eligible to apply as ACOs. The final rule added Federally Qualified Health Centers and Rural Health Clinics to the list of eligible entities. For all entities, established ACO beneficiaries will be assigned based on use of primary care services; thus, all entities applying must provide a list of practitioners who provide primary care services in their facilities.
Patient assignment	The initial proposal assigned patients retrospectively based on the plurality of primary services. This approach was changed to incorporate a hybrid of preliminary prospective assignment with quarterly beneficiary identification and reconciliation of assignment at the end of each performance year based on the patient's plurality of primary care during that year. This approach allows for the identification of beneficiaries after the initial ACO application without waiting until after 1 year of management as initially proposed. The final rule outlined not only assignment based on plurality of primary care services rendered by a primary care physician but also assignment for beneficiaries who have not had care from any primary care physician. These patients will be assigned based on plurality of primary services provided by any ACO professional (<i>i.e.</i> , nephrologists). CMS will monitor avoidance of high-risk patients and as stated in the proposed rule, will terminate ACO agreements if this behavior is revealed.
Beneficiary data sharing	In addition to sharing limited patient data (name, date of birth, sex, and health insurance claim number) at initiation of application, the frequency of beneficiary data reports to the ACO was increased from yearly to quarterly. Established ACOs will have the opportunity to ask CMS for additional patient-specific data after receiving patient consent. The ACOs are required to notify the beneficiaries of data sharing and the opportunity to decline. If the assigned beneficiary declines data sharing with the ACO, the ACO is still responsible for their care (quality, cost, and outcomes).
Quality measures	The initial 65 quality measures in five domains have been decreased to 33 measures in four domains. Unfortunately the only measure with significant impact on CKD management, microalbuminuria screening, was eliminated. During the first year, CMS will pay for reporting the measures, and during the second and third years of the agreement period, CMS will pay for both reporting and performance. Although declaring 50% of the primary care physicians as meaningful users of the EMR is no longer a condition for participation, the EMR remains a quality measure now weighted higher than the other measures. This change will allow practices to apply for inclusion in the ACO program while developing the EMR tools.

ACO, accountable care organization; CMS, Centers for Medicare and Medicaid Services; EMR, electronic medical record.

metrics were (1) not standard of care or (2) directly contraindicated for patients with advanced CKD or ESRD. Just one measure pertained directly to patients with kidney disease, and that measure (diabetes mellitus: urine screening for microalbumin or medical attention for nephropathy in diabetic patients) was among the 32 measures that CMS eliminated in the final rule. CMS did not directly respond to the concerns related to care for complex kidney disease patients in the final rule but stated its belief that “adopting restrictions or exclusions on beneficiaries with certain conditions or utilization patterns from assignment to ACOs under the Shared Savings Program would be inappropriate.” Thus, the nephrology community will need

be vigilant in how our patients will be treated in this model as the ACO program unfolds.

Specialists caring for patients with serious chronic conditions—such as ESRD—often serve as the principle care provider. How the ACO program might affect this principle care provider role for their complex patients also remained unclear. It was unclear which provider will be designated as accountable—a primary care provider participating in an ACO who the patient sees one or two times annually (a provider that CMS holds accountable for certain outcome metrics under the ACO program) or the nephrologist who consistently sees the patient in the dialysis unit (a unit that CMS holds accountable for specific and

different outcome metrics under the Quality Incentive Program)? The same question would apply to patients who are anticipating or have recently received a kidney transplant.

Although the final rule fell short of addressing the needs of patients with kidney disease, the program's premise—to incentivize more coordinated care and hold health care providers more accountable for high-quality patient outcomes—holds potential value for patients with CKD and ESRD. The recent establishment of the Centers for Medicare and Medicaid Innovation (CMMI) presents a possible pathway to apply the potentially beneficial concepts of the ACO program to kidney disease patients. Indeed, several dialysis providers of varying sizes have expressed interest in developing such models, and some have conducted independent demonstration projects to test the concept. Nonetheless, given the heterogeneity, vulnerability, and costs associated with patients with kidney disease, designing and implementing a successful integrated nephrology care delivery model within the Medicare program presents real challenges (5).

The features of any demonstration project from CMMI have not yet been revealed. Thus, the differences between the first wave of ACOs referenced above and ACOs targeted at specific chronic diseases are difficult to project beyond the obvious differences: care of the whole range of diseases centered around primary care is the general plan of the former, whereas care of specific diseases (*e.g.*, CKD) deriving mainly from specialists (*e.g.*, nephrologists) would be the design of the latter.

An ESRD Disease Management Demonstration was initiated in 2006 by CMS (5,6). It entailed three organizations each attempting to provide more comprehensive care to ESRD patients with capitated payment. The analysis available examines the first 3 years of a 5-year demonstration. The interventions beyond standard ESRD care included diabetes and cardiovascular management, nutrition therapy, and immunizations. In some measure domains—such as survival—two of three organizations saw potentially important improvements contrasted with standard fee for service and usual ESRD reimbursement, but the results were not consistent. The patient-centered outcomes were also mixed with no improvement in quality of life assessments, but patient satisfaction was positive. Costs were higher than fee for service comparators. Thus, positive signals appear in the available interim report, and analysis of the entire study should help to inform any future accountable care demonstration involving patients on dialysis.

What are the crucial considerations for an integrated nephrology care delivery model? Having considered both the primary care ACO final rule as well as the unique needs of patients with kidney disease, the ASN ACO Task Force developed a set of principles that must be reflected in a possible pilot program or demonstration (demo) project of an integrated nephrology care delivery model (*i.e.*, a specialty ACO distinct from the first wave of primary care-centered ACOs).

Nephrologists Must Maintain a Leadership Role with Oversight and Input into the Design and Execution of Any Integrated Nephrology Care Delivery Model Pilots or Demos

The leadership of nephrologists is crucial for the long-term success of an integrated nephrology care delivery model,

because nephrologists' clinical expertise is necessary to ensure that the program design will improve care for patients and reduce costs. The nephrologist is the only clinician who orchestrates and follows the dialysis patient throughout the continuum of care from CKD to progression to ESRD and transplant as well as to the outpatient dialysis clinic and hospital setting. Nephrologists possess a comprehensive understanding of kidney patient care, which neither dialysis providers nor hospitals can provide.

Furthermore, a strong presence of nephrologists (who are not employed by for-profit dialysis organizations) in the care delivery model governance structure is necessary to preserving the physician's role as the patient's advocate. Their goal should be to deliver patient-centered care with the patients' needs and choices at the forefront of the organization. Physician flexibility to individualize care becomes especially important in a shared-risk environment, in which less use may contribute to greater profit margins. Physician leadership and patient advocacy is critical to guarantee that the care delivery model remains committed to first, improving the quality of patient care and second, reducing costs. We believe strongly that the role of dialysis organizations—whether for profit, not for profit or acting independently of physicians or physician organizations—should be secondary to the role of nephrologists and other physicians caring for patients in integrated care delivery model demos or pilots for patients with ESRD as well as demos or pilots for patients CKD who have not progressed to ESRD.

If nephrologists are to provide such leadership, this role requires their acceptance of the associated responsibilities. In some cases, nephrologists will need to assert themselves in such a role when institutional practices have not appropriately recognized their leadership. Active pursuit of such positions and persistent attention will be required if nephrologists are to maintain or establish a guiding hand.

Integrated Nephrology Care Delivery Model Pilots or Demos Should Include Patients with Later-Stage CKD in Addition to Patients with ESRD to Provide Full Potential for Meaningful Benefit to Patients and Realize More Optimal Cost Savings

Kidney disease care encompasses much more than just dialysis. An integrated nephrology care delivery model should encompass a significant spectrum of kidney disease, including late-stage CKD (late-stage 4 and stage 5), dialysis, transplantation, and palliative care, addressing the fragmentation that typically characterizes transitions of care through these stages (7).

Improved care coordination could improve outcomes and reduce costs by slowing the progression of kidney disease, educating patients about their choices, planning for pre-emptive transplant or selecting the most appropriate modality type and environment, planning and initiating the most suitable vascular access type, and formulating palliative care plans where appropriate. Including late-stage CKD also mitigates the potential for preferential patient selection (cherry-picking the most financially rewarding patients). In addition, late-stage CKD care is the appropriate stage at which an integrated care delivery model should promote development of individualized care plans to help determine the best option for ESRD

care, including planning a pre-emptive transplant or electing to not receive kidney replacement therapy.

Significant population benefits may also be achieved by including the upstream spectrum of kidney disease into primary care-focused ACOs under the Medicare Shared Savings Program. This spectrum should encompass an aim to prevent or slow the progression of incipient CKD and better manage early to middle stages of CKD (stages 1–3). In many health care systems, CKD clinics have proven to be effective tools in enhancing pre-ESRD care and reducing costs for this patient population. In either case, many challenges exist to these aims. First, many people with early-stage kidney disease are unaware that they have it. Second, primary care providers do not always consult nephrologists regarding CKD patients at the appropriate time. Nonetheless, there is tremendous potential to improve pre-ESRD patient outcomes and reduce long-term costs through enhanced interactions and communications between the nephrology and primary care communities.

Integrated Nephrology Care Delivery Model Pilots or Demos Should Enable the Participation of a Diversity of Dialysis Provider Sizes and Types

Participation of a variety of dialysis provider sizes and types creates more opportunities to innovate and customize approaches to CKD and ESRD care, increasing the likelihood that the project will lead to long-term improvements in the delivery of kidney care. In an environment in which two providers care for nearly 70% of dialysis patients, opportunities for patient choice and care innovation must be protected.

To maintain the variety of dialysis organizations, the threshold for the number of patients in an integrated nephrology care delivery model should be set as low as possible.

Promoting diversity in dialysis organizations would be especially important if CMS implements a pilot model (which has a built-in sunset date) rather than a demonstration project (which barring significant safety signals, would continue in perpetuity). If a demonstration project proves successful from both patient care and financial perspectives, the early participants in the projects would have substantially more ability to negotiate contracts with ACOs or hospital systems in the future. Accordingly, from a long-term patient choice and access perspective, it becomes even more important to ensure a diversity of dialysis providers permitted to participate in a demo from the outset—especially because as a whole, independent and small dialysis organizations provide a significant portion of dialysis care.

That said, a challenge for all dialysis providers will be establishing informatics systems that can show improved care as well as reduced costs, especially savings across Medicare Parts A, B, and D, a required success metric for ACOs. The necessary information will span a broad spectrum of clinical data, dialysis delivery data, transplant success, and financial records in a variety of settings. This challenge could be especially significant for certain smaller dialysis providers, some of which are already facing difficulty providing Quality Incentive Program data to CMS.

Integrated Nephrology Care Delivery Model Pilots or Demos Must Include Opportunities/Incentives for Pre-Emptive Transplant or Promoting Transplant as a Treatment Option for Prevalent ESRD Patients

Kidney transplantation is the optimal treatment for ESRD for most patients who are healthy enough to undergo the procedure. Despite the quality of life and financial benefits, transplant rates—especially pre-emptive transplant rates—could be improved. Although the organ donor wait list time limits the number of deceased donor transplants that could realistically occur before initiation of dialysis, providers should help CKD patients consider pre-emptive living donor transplantation. An ideal system should facilitate patient education about the risks and benefits of transplantation and promote discussions with transplant surgeons, nephrologists, and their patients to yield the best choice for each patient.

An integrated nephrology care delivery model should ask participating providers to undertake efforts to ensure appropriate referral and evaluation for transplantation. Furthermore, to account for the needs of patients preparing for a transplant and during the peritransplant period, this model must offer and facilitate patient access to services beyond dialysis.

Integrated Nephrology Care Delivery Model Pilots or Demos Must Be Established in a Way That Facilitates Research and Innovation in Both Pre-ESRD and Dialysis Care

The kidney research and care community should have access to the data that are generated through these pilot programs. The dialysis industry invests very little in research and development compared with the medical and pharmaceutical industries. At the very least, an integrated nephrology care delivery model should generate databases (with greater granularity and timelines than the US Renal Data System offers) that the nephrology research community can access without restrictive barriers.

Meaningful metrics should be applied to both outcomes as well as judgment of the overall value of a CKD ACO. Integrated care should measurably improve elements, such as comprehensive CKD education, timely placement of access, elective initiation of dialysis as an outpatient, and medication reconciliation after hospitalization. Furthermore, the success of the demonstration as a whole should have rigorously prespecified comparators and outcomes that are transparent to the entire nephrology community before the initiation of demo. The analytic plan should be as rigorous as possible, with comparable standards to a clinical trial. These issues have been raised for the primary care model ACOs but are just as pertinent for a specialty ACO (8–10).

Safeguards to Monitor and Address Preferential Patient Selection or Changes in Outcomes Must Be in Place within Integrated Nephrology Care Delivery Model Pilots or Demos

In any new care delivery model or payment system, it is imperative to monitor changes in patient outcomes and access in as close to real time as possible. Even under the current dialysis care system, it is widely acknowledged that cherry-picking occurs. It is critically important that CMS or

CMMI put in place safeguards to prevent and identify preferential patient selection by providers—especially if the model includes incentives to dialysis providers to go upstream and become involved in care for patients who are not yet attributed to their care delivery model to obtain beneficial downstream effects (e.g., fistulas instead of central venous catheters).

Looking Ahead to an Integrated Care Future for Nephrology

Patients with kidney disease can receive better care with better systems. An integrated nephrology care delivery model, thoughtfully executed, offers considerable promise to deliver improved care and reduce the cost of providing it. The nephrology community should encourage and work with CMMI to design and implement pilot programs or demonstration projects that put innovative ideas to improve care to work, including monitoring of patient access and outcomes.

Importantly, the community also has a responsibility not to allow the primary care ACO program to fall from its sight. Although the primary care ACO program was not designed to care for patients with advanced kidney disease, some ACOs will inevitably assume responsibility for some of these complex patients, and these ACOs will need guidance and partnership from the nephrology community to ensure that these patients are identified and receive the individualized care that they require. The Medicare Shared Savings Program should also be held accountable to articulate a plan for ensuring that the needs of kidney and other specialized patients are met in the context of a primary care ACO.

Health care for patients with kidney disease in the United States is at a crossroads. The provision of essentially universal ESRD in the United States since 1972 has been an admirable and largely successful effort by our country to widely apply miracles of modern medicine—transplantation and dialysis. Millions of lives have been extended and improved. However, too little focus has been placed on efforts to slow progression of CKD and the cardiovascular disease linked to CKD. We suggest, instead, that new patient care models should maximize opportunities to make readily available to all CKD patients the expertise necessary to achieve better outcomes—namely, improved quality of care for patients with CKD—while at the same time, providing higher value care by delaying the need for renal replacement therapy.

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None.

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