



Making Good on ACOs' Promise — The Final Rule for the Medicare Shared Savings Program

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During my career as a practicing pediatrician, my patients and I benefited from being part of a well-managed system of care, coordinated and financed to support seamlessness and patient-

centeredness. We had an electronic health record — always available and up to the minute — which reminded me when a test or follow-up was due. For children with severe asthma, I worked as part of a team, with a home health nurse to teach skills and anticipate needs, an allergist instantly available as a coach, pharmacists to help plan care and detect errors, and advanced practice nurses to ensure 24/7 access. As a result, my patients stayed out of emergency rooms and hospital beds, remaining at home and in school, where they belonged. Function improved and costs fell.

The dedicated professionals in

the U.S. health care system work to deliver the highest-quality health care they can. But as any health care provider will tell you, our system is full of roadblocks, red tape, and frustrations that keep them from practicing the type of medicine that most clinicians envisioned when they chose their noble field.

Physicians, nurses, and other health care professionals want the support required to work with engaged patients to make the clinical decisions most appropriate to their circumstances; to collaborate with colleagues to provide a safe, seamless experience; and to be paid for keeping people well. Instead, the status quo — with

inadequate dissemination of usable clinical information, misaligned financial incentives, and in many cases, inertia — is rife with barriers to the coordinated care that patients want, providers want to give, and our unsustainable system so desperately needs.

To be sure, exactly this type of medicine is practiced every day in hundreds of places throughout the country. Innovative entrepreneurs and dedicated clinicians have found ways to break down barriers and redesign care to better help their patients and communities. But bringing the best of our system to every community in the country is the health care challenge of our time.

Eighteen months after President Barack Obama signed the Affordable Care Act, the Department of Health and Human Services (DHHS) has created a broad array of pathways for health care

Proposed Rule vs. Final Rule for Accountable Care Organizations (ACOs) in the Medicare Shared Savings Program.

Topic	Proposed Rule	Modifications in Final Rule
Transition to risk in Track 1	ACOs could choose from two tracks, each entailing a 3-year agreement. Track 1 would comprise 2 years of one-sided shared savings with a mandatory transition in year 3 to performance-based risk under a two-sided model of shared savings and losses. Track 2 would comprise 3 years all under the two-sided model.	Remove two-sided risk from Track 1. Two tracks would still be offered for ACOs at different levels of readiness, with one providing higher sharing rates for ACOs willing to also share in losses.
Prospective vs. retrospective	Retrospective assignment based on utilization of primary care services, with prospective identification of a benchmark population.	A preliminary prospective-assignment method with beneficiaries identified quarterly; final reconciliation after each performance year, made on the basis of patients served by the ACO.
Proposed measures to assess quality	65 measures in 5 domains, including patient experience of care, utilization claims-based measures, and measures assessing process and outcomes. Pay for full and accurate reporting first year, pay for performance in subsequent years. Alignment of proposed measures with existing quality programs and private-sector initiatives.	33 measures in 4 domains. (Note: Claims-based measures not finalized to be used for ACO-monitoring purposes.) Longer phase-in of measures over course of agreement: first year, pay for reporting; second and third years, pay for reporting and performance. Finalize as proposed.
Sharing savings	One-sided risk model: sharing beginning at savings of 2%, with some exceptions for small, physician-only, and rural ACOs. Two-sided risk model: sharing from first dollar.	Share on first dollar for all ACOs in both models once minimum savings rate has been achieved.
Sharing beneficiary identification claims data	Claims data shared only for patients seen by ACO primary care physician during performance year; beneficiaries given opportunity to decline at the point of care.	The ACO may contact beneficiaries from provided quarterly lists to notify them of data sharing and opportunity to decline.
Eligible entities	The four groups specified by the Affordable Care Act, as well as critical access hospitals paid through Method II, are eligible to form an ACO. ACOs can be established with broad collaboration beyond these providers.	In addition to groups included in the proposed rule, Federally Qualified Health Centers and Rural Health Clinics are also eligible to both form and participate in an ACO. In order for beneficiaries to be assigned on the basis of utilization of primary care services, these organizations must provide a list of practitioners who directly render primary care services in their facilities so that beneficiaries can be assigned on the basis of utilization of their services.
Start date	Agreement for 3 years with uniform annual start date; performance years based on calendar years.	Program established by January 1, 2012; first round of applications are due in early 2012. First ACO agreements start April 1, 2012, and July 1, 2012. ACOs will have agreements with a first performance "year" of 18 or 21 months. ACOs starting April 1, 2012, or July 1, 2012, have option of an interim payment if they report calendar year (CY) 2012 quality measures. ACO must report quality measures for CY 2013 to qualify for first-performance-year shared savings.
Aggregate reports and preliminary prospective list	Reports will be provided at the beginning of each performance year and include: name, date of birth, sex, and health insurance claim number.	Additional reports will be provided quarterly.
Electronic health record (EHR) use	Aligning ACO requirements with EHR requirements, 50% of primary care physicians must be defined as meaningful users by start of second performance year.	No longer a condition of participation. Retained EHR as quality measure but weighted higher than any other measure for quality-scoring purposes.
Assignment process	One-step assignment process: beneficiaries assigned on the basis of a plurality of allowed charges for primary care services rendered by primary care physicians (internal medicine, general practice, family practice, and geriatric medicine).	Two-step assignment process: Step 1: for beneficiaries who have received at least one primary care service from a physician, use plurality of allowed charges for primary care services rendered by primary care physicians. Step 2: for beneficiaries who have not received any primary care services from a physician, use plurality of allowed charges for primary care services rendered by any other ACO professional.
Marketing guidelines	All marketing materials must be approved by the Centers for Medicare and Medicaid Services (CMS).	"File and use" 5 days after submission and after certifying compliance with marketing guidelines; CMS to provide approved language.

providers to begin — or in many cases, accelerate — their care-improvement journey in partnership with the Medicare and Medicaid programs and in synergy with the private sector. Today, the DHHS is taking its next major step by finalizing the rules for the establishment of accountable care organizations (ACOs) under the Medicare Shared Savings Program created by Section 3022 of the health care reform law.

ACOs are voluntary groups of physicians, hospitals, and other health care providers that are willing to assume responsibility for the care of a clearly defined population of Medicare beneficiaries attributed to them on the basis of patients' use of primary care services. If an ACO succeeds in both delivering high-quality care or improving care and reducing the cost of that care below what would otherwise have been expected, it will share in the savings it achieves for Medicare.

Under the ACO model, Medicare beneficiaries are still free to seek care from any Medicare provider they wish. Indeed, Medicare beneficiaries should find their care experience enhanced by a program that supports providers in engaging with their patients to deliver on the three-part aim: better care for individuals, better health for populations, and lower cost growth through improvements in care.

The DHHS proposed its initial set of guidelines for ACOs on March 31, 2011, and sought widespread comment on both the direction and the details of this important new program for Medicare. We at the Centers for Medicare and Medicaid Services (CMS) received more than 1200 formal comments from throughout the health care community, supple-

mented by feedback at dozens of informal listening sessions. The vast majority of the comments we received were supportive of the vision of the Shared Savings Program and optimistic about the potential for ACOs to be a force for change in our broken health care system. However, numerous suggestions were also offered for improvements to the proposed rule that would lead to a larger, more pluralistic set of ACO participants without compromising patient outcomes or choice. In particular, commenters asked CMS to reduce barriers to entry by streamlining governance and reporting burdens on potential ACOs; improve the potential financial return for ACOs willing to make the necessary, and often substantial, investments to improve care; and ensure beneficiary protections.

In response, CMS is making several significant changes in its final rule to strengthen the ACO program for providers and beneficiaries alike (see table). Major changes include providing better, and more timely, information to ACOs at the outset of the performance year through preliminary prospective alignment of beneficiaries (while retaining a retrospective reconciliation to ensure that ACOs are measured on the basis of the patients they actually care for during the year); retaining a strong monitoring and quality-measurement mechanism while streamlining the metrics to focus on what matters most, including reducing the total number of quality measures by about half; allowing start-up ACOs to choose a "savings only" track without financial risk during their initial contract period; sharing savings with successful ACOs on a "first dollar" basis when the ACO achieves meaningful savings for

the Medicare program and improves care or provides high-quality care; and creating a pathway for full participation of federally qualified health centers and rural health clinics that provide a primary care safety net for Medicare beneficiaries in underserved areas.

Taken together, these changes and numerous others create a more feasible and attractive on-ramp for a diverse set of providers and organizations to participate as ACOs. In addition, the Center for Medicare and Medicaid Innovation is announcing today an advanced payment initiative that will allow small physician practices and rural community hospitals that face particular challenges in forming ACOs to receive up-front access to needed capital.

For established organizations with a track record of providing robust coordinated care, the CMS innovation center is offering a pioneer ACO program designed to encourage and support the next wave of innovation from vanguard organizations that are positioned to help realize the full potential of the ACO model. And for organizations and clinicians not yet prepared to make the transition to ACOs, the DHHS is offering a menu of alternative options — including a comprehensive primary care program, bundled payments for care improvement, and a community-based transitional care program — that all seek to provide the incentives and supports necessary to move the mainstream of U.S. health care toward accountable care.

Whether provided through ACOs or an alternative innovation opportunity, coordinated care is meant to allow providers to break away from the tyranny of the 15-minute visit, instill a re-

newed sense of collegiality, and return to the type of medicine that patients and families want. For patients, coordinated care means more “quality time” with their physician and care team (a patient’s advocate in an increasingly complex medical system) and more collaboration in leading a healthy life. And for Medicare, coordinated care represents the

most promising path toward financial sustainability and away from alternatives that shift costs onto patients, providers, and private purchasers.

We believe that today’s ACO rule is the next step in our shared commitment to a better, more lasting health care system. We look forward to being a trusted partner in our nation’s journey

toward patient-centered, coordinated care.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

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Getting Moving on Patient Safety — Harnessing Electronic Data for Safer Care

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More than a decade ago, the Institute of Medicine released its famous report *To Err Is Human*, which set an ambitious agenda for the United States to reduce the number of Americans who were hurt or killed by medical errors and adverse events. In response, a series of new initiatives was launched, including the funding of new research on ways of making care safer and encouragement of programs shielding health care providers from liability if they reported adverse events. Federal agencies set up patient-safety organizations and established ambitious patient-safety goals; accrediting organizations set aggressive patient-safety standards; and providers hired patient-safety officers and implemented numerous patient-safety initiatives.

So what are the fruits of these efforts? Recently, we have received some deeply disappointing news: three studies have called into question whether we’ve made any progress at all. Landrigan et al. found that rates of injury due to medical error had remained es-

entially unchanged between 2000 and 2008 at 10 North Carolina hospitals.¹ A report from the Inspector General of the Department of Health and Human Services (DHHS) revealed that Medicare patients experienced substantial harm in U.S. hospitals as recently as 2008.² Finally, Classen and colleagues found that almost one in three patients are harmed during their hospital stay and that traditional approaches to measuring adverse events, whether using voluntary reporting or patient-safety indicators, substantially underestimate the events’ frequency.³ If the United States has made progress in patient safety, it has been inadequate.

The primary reason for insufficient progress is the lack of a robust measurement program: there are still no nationally agreed-on methods for systematically identifying, tracking, and reporting adverse events. Here, the patient-safety movement can learn from the quality-improvement efforts that predate it. In the 1990s, emerging evidence suggested that providers were inconsistent in

their adherence to evidence-based treatments such as the use of aspirin for patients with acute myocardial infarction. Efforts by the Joint Commission for the Accreditation of Healthcare Organizations to systematically measure performance and give feedback to hospitals, coupled with subsequent efforts to publicly report performance on these measures, led to dramatic improvements in compliance.⁴ In the few areas of patient safety that have seen demonstrable improvement (e.g., catheter-related bloodstream infections), the changes are due, at least in part, to robust measurement programs, such as those run by the Centers for Disease Control and Prevention. In other areas, inadequate measures have hindered progress, and patients continue to suffer from the consequences of unsafe care.

Although there is a shortage of good patient-safety metrics, poor-quality measures are plentiful. The best known among these are patient-safety indicators, which use billing data to identify potential complications during a hos-