Key Elements of the Proposed Regulations

On March 31, the Obama administration released its long-anticipated proposed rules governing accountable care organizations, a mechanism that will pay providers a share of savings based on their ability to lower costs while meeting quality metrics.

The 429-page document allows groups of ACO professionals with a minimum of 5,000 beneficiaries to apply for one of two risk models in order to benefit from shared savings over the three-year program. In the first model, providers would share savings of 50% in all three years, but would be at risk in year three for any losses that exceed 2% of the benchmark established by the Centers for Medicare & Medicaid Services.

In the second model, ACOs could receive a higher percentage of shared savings, up to 60%, but would be at risk of absorbing losses in each of the three years if their expenditures exceeded the CMS benchmark. Beneficiaries would be retrospectively assigned to the ACO, to reduce the possibility that providers may avoid patients with multiple diagnoses. But this requirement concerns many healthcare
organizations, which say they won’t know which patients they should focus on.

In both concepts, the goal is that many types of providers, including hospitals, primary care providers, specialists, and long-term care facilities, would coordinate beneficiaries’ care to reduce duplication and improve prevention and wellness through a system that scores performance on the basis of 65 quality metrics.

Significant elements of the program require 50% of the primary care physicians in the ACO to meet Stage 1 HITECH meaningful use criteria, and allow CMS to withhold 25% of an ACO’s shared savings bonus in each year to cover any future losses.

The Federal Trade Commission and the Department of Justice released a second document setting forth proposed rules by which ACO candidates would be deemed in compliance with antitrust regulations.

Providers have until June 6 to submit comments to both proposals. The ACO model is set to begin Jan. 1, 2012, although because of concerns that many organizations may not be able to start that soon, the administration allows a later start date of July 1, 2012, with a 3.5-year period.

Between 75 to 150 groups are expected to initially satisfy the requirements. Startup investment and first-year operating expenditures for a participant in the Shared Savings Program are estimated by CMS at about $1.75 million per ACO.

Administration officials anticipate savings between $510 million and $960 million in the first three years, with total bonus payments of $800 million and total penalties paid to CMS of about $40 million.

**ACO TERMS TO KNOW**

**The Paperwork Reduction Act of 1980**
The proposed ACO rules specifically say that the PRA, which strives to minimize the paperwork burden resulting from the collection of information by or for the federal government, would not apply to ACOs.

**Safety Zone**
Think safe harbor. This is the promise that federal antitrust agencies, “absent extraordinary circumstances” will not challenge the eligibility of an entity that meets other ACO criteria if its provider participants fall into this safety zone. To do so, they must have a combined share of 30% or less of each common service in an ACO participant’s primary service area. The zone is extended for ACO participants who have between 31% to 50% share of a common service area, “if it avoids specified conduct.” A greater than 50% share, however, constitutes “a valuable indication of an ACO’s potential for competitive harm.” There are exceptions for providers in Rural Service Areas.

**Primary Service Area**
This is defined as the lowest number of contiguous postal ZIP codes from which the ACO participant draws at least 75% of its patients for that service.
Proposed ACO Guidelines Alone Will Not Fix a Flawed System

THE NEED TO MODERNIZE THE healthcare system and focus on more integrated and collaborative care is at the heart of health reform. The long-overdue draft of Centers for Medicare & Medicaid Services accountable care organization proposed rules were released on March 31, accompanied by companion sets of regulations, including one from the FTC about antitrust implications, took us one step closer to what is needed.

The release of the proposed rules is a critical step in attempting to better control escalating costs and is a positive step in bringing together various participants in health communities to align their objectives around information, incentives, workflows and outcomes for patients.

The negative implication—and this is not per se about the regulations but more about the realities of the healthcare system as it functions today—is that the new ACO guidelines, in and of themselves, do not go far enough to “fix” a health system that is unsustainable.

Growth in ACOs, as guided by the Patient Protection and Affordable Care Act, will be built on a regulatory framework...
that, while attractive to some participants, will be less so, or even prohibitive, to others. This is particularly true for some physicians and patients/consumers who, standing at the front lines in managing health concerns, need to be fully engaged in an ACO to ensure its success. In other words, systematic improvements must start at the local level, which means making sure smaller players—not just large, high-performing systems—can participate to create broad market coverage, and that patients must be central to, and more engaged in, the care delivery process.

In the short term, the ACO proposed rules start the transition to more collaborative delivery of care and demonstrate that making it affordable is not just a lofty idea anymore, but a necessity. This means that all stakeholders must get involved and learn to create viable, long-term solutions.

And it’s important to note the role technology plays in these long-term solutions. Technology has certainly matured over the last two decades when healthcare reform first made national headlines. Health information technology is being used on a broader scale, and as the underpinning to collaborative care, it is also the foundation of a Sustainable Health Community.

A Sustainable Health Community, in our view, is a long-term vision for truly effective and cost-efficient health in which all stakeholders, including consumers, are involved in the health and well-being process. In many communities around the country, we are the architects of a more comprehensive model to design, build, and operate Sustainable Health Communities.

Our model is based on elements that incorporate many of the same tenets of an ACO while also working to effectively engage multiple payers, integrate pharmacies, and ensure consumer engagement. Most importantly, there is a general principle that organizations will meet specific quality metrics, adopt improved care processes, share risk, and provide system-wide incentives for population health and wellness.

This is a more comprehensive vision to collaborative care that is going to make the difference from a cost and quality standpoint. When you look at initial results from the Medicare ACO pilots including our own analysis of those and the

“In the short-term, the ACO proposed rules will create a framework for the industry to start to transition from silos to a well-coordinated and aligned system.”

Andy Slavitt, CEO, Ingenix
Dartmouth/Brookings ACO pilots, the 10 Medicare Physician Group Practice demonstration sites and the five Dartmouth/Brookings sites, the majority of savings at the pilot sites occurred in outpatient services.

However, inpatient savings were still not readily available and proved to require more widespread process improvement in order for pilots to gain a break-even point within three to five years. The guidelines—as proposed—may not do enough to bend the cost curve, particularly if you examine the hurdles they have to overcome to achieve shared savings.

While the results may seem discouraging at first, it’s important to acknowledge that these pilot demonstrations have had to work within a flawed system. It’s clear the ACO model is one important framework to drive down the cost of care, but it must also be realistic in addressing systemic issues.

Whether or not CMS can address these broader issues, change is necessary and the direction is clear. CMS has helped spark a movement that is gathering momentum and the private sector is already taking a leadership role in defining the basic execution requirements necessary to launch and maintain a successful ACO.

As we reflect on what is going to take us forward as an industry, an organization’s strategic leadership must begin to answer some critical operational questions:

» How do we start thinking about aggregating a community-wide view of patient information?
» How do we create an environment of transparency and fairness in financial transactions?
» How is risk in our community appropriately distributed to align incentives and behavior?
» What are some of the strategies to manage population wellness and how do we track improvements?
» How do I align my network around a common value set?
» How do I get members/patients and keep them healthy?
» Once I can access data, what can I do with it?
» How do I identify the patients or processes that drive the highest costs?
» How do I begin to identify gaps in financial and operational processes that impact revenue/profit, slow cash flow, and complicate transactions?

ACOs represent an exciting shift in the delivery of care—a change that will touch virtually every stakeholder that provides, receives, and funds care. It’s clear that there is no single path to the future; however, successful deployments will require new levels of collaboration, foundational tools and technologies, and innovative approaches to health delivery.

Andy Slavitt, CEO, Ingenix
Impact Analysis

How the ACO Regulations Can Be Improved

BY CHERYL CLARK

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How the ACO Regulations Can Be Improved

Perhaps the anticipation raised expectations, but now that the federal government has released its proposed regulations for accountable care organizations, the response from healthcare leaders is lukewarm. Yes, there is praise for parts of the plan, but there also is disappointment and surprise that there weren’t more carrots than sticks.

Indeed, many of the details embedded in the 429-page document released March 31 that sets forth requirements to qualify for ACO status are deterring many leaders from signing up unless the model is significantly changed. They say they plan to express their concerns during the comment period that ends June 6 in the hope of getting more favorable terms.

They embrace the quality metrics and the primary care focus to coordinate service in a way that ultimately provides better care at a lower cost. And they appreciate that there are two roads in to qualify, one with no front-end risk, the other with front-end shared savings and shared losses.

“The entire attempt to address the fragmentation in the system is positive,” says Chris Van Gorder, president and chief executive officer of Scripps Health in San Diego. But what the Centers for Medicare & Medicaid Services proposal would do is “require, in some cases, the creation of a new entity or infrastructure, which adds cost; it doesn’t decrease cost. I am, at least right now, not convinced that there will be many organizations that will decide to do this at the beginning.”

The overarching concerns expressed by many healthcare executives are the complexity and the expense of the preparation, as well as the cost of the buy-in, especially for providers who have not developed an ACO model so far.

“I think there’s a very high bar that’s set in these regulations,” says Thomas Graf, MD, chairman of Community Practice Service Line for Geisinger Health System in Danville, PA. “They’re very detailed, and somewhat prescriptive, although there’s a mention...
that if there's an alternate idea, and you can show how your proposed alternative meets these goals, they would consider it.”

The requirement that an ACO opting to go with the model that would absorb risk on Day 1 must achieve a savings of 2% above the set threshold before the ACO could participate in the shared savings, Graf says, “is a significant hurdle for practices to overcome. I think people should look at that very carefully as they size their ACOs and make sure they have the ability to truly change culture and impact the way care is delivered.”

The regulatory framework of the ACO model will appeal to some participants, but will be less attractive or even prohibitive to others, such as physicians and patients, who need to be fully engaged in an ACO to ensure its success, according to Andy Slavitt, CEO of Ingenix, the Minnesota-based health information and analytics, technology, services, and consulting company. He acknowledges that the proposed regulations represent a “critical first step” but “do not go far enough.”

“We believe that systematic improvements must emanate from the local market, which means making sure smaller players—not just large systems—can participate to create broad market coverage, and that patients must be central to, and more engaged in, the care delivery process,” Slavitt says.

The cost of participation could limit the ability of smaller organizations, and the estimates themselves may not be realistic. “Many of the complexities and process-based requirements, as well as the investments that will likely be needed for most organizations to be high-performing ACOs will be excessive in my view, and they will likely be much greater than the $1.7 million CMS estimates per ACO that’s described in the regs,” says Craig Samitt, MD, president and CEO of Dean Health System in Madison, WI.

“I think $1.7 million is a far underestimate of the cost of implementation, legal services, investments, process improvement strategies, and staffing strategies.”

**ACO TERMS TO KNOW**

**Retrospective Assignment**
To eliminate the possibility that an ACO would pick the healthiest, easiest-to-manage patients, groups of 5,000 beneficiaries would be retrospectively assigned to each ACO by CMS. Here’s CMS’ explanation from page 114 of the regulations:

“One reason for this is that we believe that the ACO should be evaluated on the quality and cost of care furnished to those beneficiaries who actually choose to receive care from ACO participants during the course of each performance year. Another reason for retrospective assignment is to encourage the ACO to redesign its care processes for all Medicare FFS beneficiaries, not just for the subset of beneficiaries upon whom the ACO is being evaluated.”

**Procompetitive**
ACOs that are procompetitive are likely to be approved and not endure any further scrutiny from the DoJ or the FTC. Likewise, anticompetitive ACOs will not be approved, or will subsequently face review.
Some don’t think it’s equitable or practical that they won’t know which Medicare beneficiaries they’ll be judged on until at least a year after the program is under way. And many expressed concern that there just isn’t enough time between now and Jan. 1 for the final regulations to come out, for them to apply, be approved, and have all these pieces fit in place, although the regulations do allow for ACOs to begin July 1, 2012, and have a 3.5-year agreement.

Van Gorder expressed that concern, among others. “The government is trying to put a politically correct managed care system of healthcare together requiring the hospitals or the ACO to assume both financial and quality responsibility for patients without even letting them know who those patients are until retrospectively.”

That sentiment was echoed by Richard A. Hachten II, president and chief executive officer of Alegent Health in Omaha, NE. “It’s appropriate that we’re going to be managing people’s health differently going forward; it’s the financial risk part of it and not being able to do that as effectively as one could if you knew which patients you were working with, and could do a more effective job in coaching the use of healthcare resources,” he says. “So we think there’s a significant amount of unmanageable risk built into the way it’s set up currently.”

But Samitt disagrees. ACOs, he says, should be expected to deliver the same high-quality, value-based care to all Medicare beneficiaries regardless of whether they are eventually assigned in the ACO.

“I know this is controversial,” Samitt says. “But if we in the industry truly believe in the merits of delivering patient-centric, patient-centered care...
coordinated, and value-based care, we should deliver that model of care to all patients, irrespective of whether we know in advance whether they’re part of the ACO. While there are some downsides to this retrospective assignment, the pros outweigh the cons.”

Hachten says that he knows “it’s been very deliberate on the part of CMS to allow a lot of freedom for Medicare beneficiaries and how they choose to use providers. But I think it’s going to be critical, long term, in both managing people’s health and managing expenses to have individual incentives for people, and that dimension is simply lacking in the regs.”

Van Gorder says he’ll hold his system back from applying for Medicare ACO status unless the regulations undergo significant change. “Frankly, I was surprised. I thought there would be more carrots, not so much stick.”

Jay Cohen, MD, executive chairman of Monarch Healthcare in Orange County, CA, says he was “gratified to see that CMS actually did get it, that risk-bearing is required for the ACO notion to be effective. For a long time we were hearing that there was going to be a shared saving program only. And we believe that if you don’t put the delivery system at risk, you don’t get their attention.”

But the negatives on the flip side, he says, outweigh the positives in the proposed regulations, and may prevent his organization from opting to be an ACO. “The way the proposed regulations are written will not work,” he says.

“The good news is that organizations that are mature and sophisticated could handle the proposed model, although I’m not sure they’re going to want to,” Cohen says. “My concern is that organizations that are not mature, that are not sophisticated, are not going to be able to handle it, so I think you’re killing the whole idea of having this be adopted on a large scale nationally.”

**ACO TERMS TO KNOW**

**Mandatory Antitrust Review**
An ACO that does not qualify for the rural exception is subjected to a mandatory federal scrutiny if its share exceeds 50% for any common service that two or more independent ACO participants provide to patients in the same PSA. One exception to mandatory antitrust review could be employed if the ACO can supply CMS with a letter from either the DoJ or the FTC “stating that the reviewing Agency has no present intention to challenge or recommend challenging the ACO under the antitrust laws.”

**Group Practice Reporting Option**
The GPRO is the method by which CMS proposes to calculate results for the first year of the program. The GPRO is similar to the Physician Quality Reporting System. CMS says the GPRO tool is a mechanism by which beneficiaries’ lab results and other clinical information can be reported to CMS for determining shared savings. Measures reported under the GPRO must consist of at least 411 assigned beneficiaries per measure set/domain, and if the pool of eligible beneficiaries is less than 411 for any measure set or domain, then the ACO will have to report on 100% of all assigned beneficiaries.
Among other things, the inability to know which patients are in the ACO and which aren’t, Cohen says, makes it “very, very hard to have any impact on a population.

"My sense is the reason they did that is because CMS would like to see the benefit of the activity impacting the entire Medicare Part A and Part B population. And well, yeah, that's great. I'd like to see that as well. But you do that by getting them into the program. You don't try to fake it and say okay, we're not going to tell you who you're managing. Do all these good things on everybody whether they're in or they're out."

George Halvorson, chairman and chief executive officer of Kaiser Foundation Health Plan and Kaiser Foundation Hospitals, which has 8.8 million members nationally, says his system does not plan to apply and will stay with prepaid Medicare Advantage.

Kaiser, he says, already has a much more advanced team approach to care that goes beyond the four walls of the system with a model that's not based on fee for service. "We're already there and we're giving great care. We're cutting the number of heart attacks in half; we're cutting the number of broken bones in half."

Halvorson does say that the ACO’s focus on team care is a positive step and should help reduce the cost of care, but falls short of the Medicare Advantage model.

"I think the payment structure defined in the ACO regs is an interim step toward getting people to function as an accountable care organization. And I think it is directionally correct. It is not as

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**ACO TERMS TO KNOW**

**Domain**
This is how CMS categorizes the 65 quality metrics whose scores will be basis for determining shared savings of up to 60%, or 65% if the ACO includes federally qualified health centers or rural health centers. There are five domains.

1. Patient or caregiver experience includes seven measures.
2. Care coordination includes 16 measures.
3. Patient safety includes two measures.
4. Preventive health includes nine measures.
5. At-risk population/frail elderly health includes 31 measures. This domain focuses on six categories of health conditions or status: diabetes, heart failure, coronary artery disease, hypertension, chronic obstructive pulmonary disorder, and frail elderly.

**ACO Professional**
This is a physician or osteopath, physician assistant, nurse practitioner, or clinical nurse specialist and not limited to those dedicated to primary care.

**Eligibility**
The proposed rule says that the following groups are eligible to participate in an ACO:
- ACO professionals in group practice arrangements
- Networks of individual practices of ACO professionals
- Partnerships or joint venture arrangements between hospitals and ACO professionals
- Hospitals employing ACO professionals
- Other groups of providers determined to be appropriate by the Secretary of Health and Human Services.
In the short term, Slavitt says, “the ACO regulations will create a framework for the industry to start to transition from silos to a well-coordinated and aligned system. The regulations are a clear demonstration that affordable healthcare is not just a lofty idea anymore but a necessity that must be tackled. This means that all the people that influence patient care—payers, physicians, providers—must get involved, and learn how to collaborate to create viable, long-term solutions.”

Technology will play a big part. “This isn't 1992, when healthcare reform first made national headlines, but the infrastructure wasn't in place to support it,” Slavitt says, noting that health information technology is being used on a wide scale today and serves as the underpinning to collaborative care.

Samitt of Dean Health also emphasizes collaborative care and is pleased with the array of 65 quality metrics that will be used to evaluate system performance. ”These quality metrics will create a common yardstick by which quality, service, and efficiency are measured.”

He is pleased that “the regulations’ focus is on the primary care centric delivery model. It pays credence to the notion that the primary care patient-centered medical home is a critical component of delivering value-based care. Primary care has not received the focus, the respect, and the recognition for the critical role they play in delivering comprehensive, collaborative, and preventive care.”

Geisinger Health System, one of the 10 Physician Group Practice demonstration sites, plans to stay with that PGP model, called Transitions, for another two years, especially since the new rules for the second portion of that program were just released, Graf says. But that would just apply to care “within Geisinger’s walls.” Graf adds that he hopes the system can form a separate ACO type of organization that merges Geisinger hospitals, specialists, and other Geisinger-affiliated providers with providers outside Geisinger, "to develop a more complete ACO model.

"Clearly that’s advantageous because if you think about the threshold, and some of the statistical analyses, obviously having more patients is better. It lowers your threshold and provides a lot more stability to the actuarial pieces of the model," Graf says.

Graf also notes that some organizations will have to endure a 25% withhold, which means that in order to make sure new ACOs are able to manage any losses, they’ll retain one-quarter of shared savings. "To the extent you’re a startup ACO, you have to put in costs now, presumably something to improve the care that you’re delivering on both the quality and cost side. You incur costs on Day 1,” he says.

Graf explains: "Let’s say that in the first year, you qualify for shared savings of $2 million. [CMS says] we’ll pay you $1.5 million and we’ll retain half a million in case in the second year you have $300,000 of losses, which will come out of the $500,000."
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Hachten says that in concert with ACO development, he expects Alegent—which already has many ACO-like initiatives under way—“will probably pick up the pace on some of those, now that we know what the expectations will be.” Adopting ambulatory electronic medical records, he says, “will ultimately be extremely critical. We have to step back and see if we can move that process at a faster pace.”

Van Gorder emphasizes that rather than this flawed ACO model, CMS would get better results by expanding bundled payment incentives to include hospital care. “That will get faster and maybe better results than by trying to push the ACO too fast,” he says.

He also says that he was quite surprised the regulations impose a penalty for lack of performance on cost controls “right at the beginning of this grand experiment. That was expected over time, but [not] for a startup program that is extremely complicated and far-reaching. One would have thought the feds would have done all they could to attract and incentivize healthcare providers and suppliers to take this risk.”

Slavitt notes that most of the savings being realized in ACO pilot programs is in outpatient services. “According to our analysis, inpatient savings were still not readily available and proved to require more widespread process improvement in order for pilots to gain a break-even point within three to five years. The guidelines—as proposed—may not do enough to bend the cost curve, particularly if you examine the hurdles that they have to overcome to achieve distributable shared savings.”

“He says the CMS proposal will need to address systemic issues that impede success. “The final regulations must reflect what we have all learned from successes achieved by market-led models that have emerged with hospitals, physicians, and payers. Real-world experience from these models is defining some of the basic execution requirements necessary to launch and maintain a successful ACO.”

Industry leaders expect the regulations will be modified once CMS hears the volume of concerns during the comment period. And in the meantime, healthcare leaders are trying to do what the federal government wants in the long run, which is to cut costs, become more efficient and streamlined, and make tweaks or even massive changes in their systems to better manage all aspects of care for their patients. A

Cheryl Clark is senior quality editor for HealthLeaders Media.
Additional Resources

For more information about our Impact Analysis participants, go to:

**Alegent Health**
www.alegent.com

**Kaiser Foundation Health Plan**
www.kaiserpermanente.org

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www.deancare.com

**Monarch Healthcare**
www.monarchhealthcare.com

**Geisinger Health System**
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Ingenix is one of the world’s leading health information and analytics, technology, services and consulting companies. Ingenix helps clients across the health ecosystem build Sustainable Health Communities that are more connected, intelligent and aligned in order to enable truly effective and cost-efficient health in which all participants of a community function in harmony to achieve enduring community health: optimized care quality, cost and consumer experience. Ingenix has a deep understanding of the needs of the multiple participants across the health ecosystem, enabling it to deliver collaborative solutions that provide the insights and care to help build sustainable health communities.

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Additional Materials

**The Physician’s Place in the ACO**

Development of accountable care organizations may be critical to holding down costs and improving quality. But how will doctors’ roles change?

[www.healthleadersmedia.com/content/MAG-258879/The-Physicians-Place-in-the-ACO](www.healthleadersmedia.com/content/MAG-258879/The-Physicians-Place-in-the-ACO)

**ACOs: From Volume to Value**

To understand the transformative potential of what ACOs could be requires you to poke at the definition of accountable. You have to ask two questions: Accountable to whom, and accountable for what?


**Healthcare Leaders Prep for the ACO Model**

As the reign of fee-for-service draws to a close, healthcare leaders are stepping up efforts to develop accountable care strategies.


**Healthcare Reform Spawns Daunting Regulations**

The volume of new regulations required by healthcare reform legislation is daunting, but what has healthcare leaders especially concerned are the particulars, which are still under development.

[http://www.healthleadersmedia.com/content/MAG-260989/Healthcare-Reform-Spawns-Daunting-Regulations](http://www.healthleadersmedia.com/content/MAG-260989/Healthcare-Reform-Spawns-Daunting-Regulations)

**Your Move: Hospitals Are Predicting, Adapting to Change**

The business models that will emerge in the era of healthcare reform are still unclear, but leading hospitals and health systems are already positioning themselves to adapt when they do come into focus. They’re taking the first steps toward becoming accountable care organizations even before anyone knows for sure what an ACO will look like—or even if they’ll ever come to fruition.


**Ingenix’s ACO Resource Center**

Keep up to date on the CMS proposed rules, integrated care delivery models in action, and the latest thinking about making new delivery sustainable by accessing the resource center at [www.ingenix.com/ACOs](www.ingenix.com/ACOs).

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