

Healthcare reform is creating significant changes in how care is delivered to Medicare patients. And this will have far-reaching effects throughout healthcare, leading to a potential shift in pharmaceutical companies' customers.

Medicare patients is changing as a result of the Affordable Care Act (ACA) of 2010. Accountable care organizations (ACOs) are groups of providers that aim to provide integrated and coordinated care to Medicare patients that is driven by outcomes, and, if successful, will share in any savings achieved.

ow healthcare is delivered to

Healthcare delivery will change to be more evidence- and protocol-based, and this will drive a trend of providers partnering with payers to yield outcomes rather than encounters, says Bill Fera, M.D., healthcare advisory services practice, at E&Y.

"Traditionally, our healthcare system creates incentives that lead to 'encounters,'" Dr. Fera says. "Currently, there is not enough of the quality or outcomes basis of the reimbursement for that encounter. We are transitioning to an incentive model that looks at the overall outcomes of those encounters and how providers are interacting with patients. Right now, if providers are not seeing patients face to face, they are not getting reimbursed, and every minute spent on care coordination activ-

ities such phone calls or emails or follow-up with other practitioners is not currently reimbursed."

While ACOs are primarily aimed at improving the quality of care for a government beneficiary — Medicare patients — the commercial healthcare sector is actively engaged in applying this concept across the healthcare continuum, says Kent Rogers, VP, managed markets, at Acorda Therapeutics.

"The ACOs will use a hospital-based model and may mirror already existing structures, such as Kaiser Permanente or Geisinger Health Plan, where physician care is largely integrated," he says. "The hope is that the quality of healthcare will be improved if physicians across multiple specialties coordinate care of patients."

Medicare ACOs would take part in the Medicare Shared Savings Program implemented as part of healthcare reform. But to share in the savings, an ACO must meet certain quality standards. CMS has established 33 quality measures relating to care coordination and patient safety and appropriate use of preventive health services.

Robert Hollis, principal, managed markets

services division, at IMS Health, says ACOs are the first step in aligning cost and care incentives so that providers will have a stake in the cost of the services, the drugs they recommend for patients, and ultimately the resulting outcomes.

"The Medicare Shared Savings Program is giving ACOs an opportunity to share in these cost savings and provide a full spectrum of care to patients," he says. "For an ACO to be effective, it's going to require excellent coordination of care, investment in state-of-the-art health IT, implementation of protocol-driven care models, and performance measurements against quality standards."

ACOs are the "cousins" of integrated delivery systems, says Angeliki Cooney, principal, brand and commercial strategy, at IMS Health.

"The private sector, in terms of delivery of care, is changing to emulate the ACO concept," she says. "In fact, more than 80% of hospitals right now are within some sort of IDN, more than 60% of group practices, and at least half of the physicians in the country are part of an integrated network. If that pattern continues, the ACO model will probably have a very wide ranging effect on healthcare delivery."

Ms. Cooney says a shift in healthcare delivery from managed care to integrated delivery systems and ACOs will mean that pharmaceutical companies will need to reconsider their customers going forward.

"Pharmaceutical companies are trying to experiment with different ways to go to market," she says. "IDNs and ACOs are introducing

completely different needs. Pharmaceutical companies are still working on a share-of-voice model, where the physician is the only customer. More and more, they are realizing that no matter what the potential of the physician, no matter how many times reps call on a physician, it's not always going to make a difference with regard to a sale."

Ms. Cooney says pharmaceutical companies have to look at who their customers are in a more holistic way.

"This will take a lot of analytical work that is very different from what pharmaceutical companies are doing now," she says. "And then they need to figure out what clients need and how to make the entire process a better experience for the patient and the customer."

Mr. Rogers says this shift to more integrated care may change who the decision markers are with an integrated health system.

"In the 1990s and early 2000s, physicians were coalescing buying power throughout the mid-Atlantic, the Southeast, and the Midwest, much like the West Coast had done for years," he says. "Pharma's managed markets groups had developed field teams of account managers focusing on these groups, anticipating global risk arrangements that would spawn drug formularies within each medical group. What we found is that this was not the case and the focus shifted to where the flow of the dollar has largely remained: health plan/PBM decision makers."

ACOs vs. HMOs

Industry experts say Medicare ACOs are different from HMOs and other forms of managed care, although they employ concepts that are similar and that were first used in the private market.

An accountable care organization is a provider-based entity that assumes some risk related to cost and quality vs. a purely payer-based entity, says Peyton Howell, senior VP, AmerisourceBergen and president, global sourcing and manufacturer relations.

"An ACO typically includes primary care physicians and it can also include a wide range of specialists," she says. "Often hospitals are at the center of integrating all of those care models. Together those providers are accepting the cost and risk of providing care to a defined

Medicare population, but if this actually works, it will be adopted more widely, creating a new paradigm that can probably work for everyone.

ANGELIKI COONEY / IMS Health



pool of patients and also accepting responsibility for quality."

Ms. Howell says the federal government is trying to incentivize more providers to work in collaboration in models that are much more focused around the patient.

"That's what I think is exciting about ACOs," she says. "The concept is to have more of a patient perspective so that the hospitals and the physician offices are coordinated and connected and everyone has the information to make the best treatment decisions."

Scott Sarran, M.D., chief medical officer,

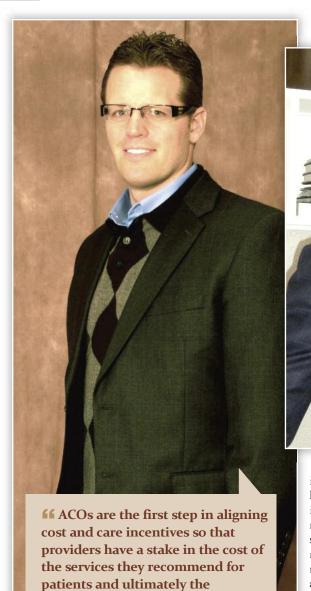
What is an ACO?

Accountable care organizations (ACOs) are groups of doctors, hospitals, and other healthcare providers, that come together voluntarily to give coordinated high quality care to their Medicare patients. ACOs have entered into agreements with Centers for Medicare and Medicaid Services, taking responsibility for the quality of care they provide to people with Medicare in return for the opportunity to share in savings realized through high-quality, well-coordinated care.

The Medicare Shared Savings Program (MSSP), and other initiatives related to ACOs, is made possible by the 2010 Affordable Care Act. Federal savings from this initiative could be up to \$940 million over four years. To ensure that savings are achieved through improving care coordination and providing care that is appropriate, safe, and timely, an ACO must meet quality standards. CMS has established 33 quality measures relating to care coordination and patient safety, appropriate use of preventive health services, improved care for at-risk populations, and patient and caregiver experience of care.

As of July 2012, there were 154 ACOs serving more than 2.4 million Medicare beneficiaries.

Source: Health and Human Services



government program, Health Care Service Corp., which launched an ACO partnership in 2010, says ACOs are an extension of many arrangements that have been in place for years.

ROBERT HOLLIS / IMS Health

resulting outcomes. ""

"What's different now is the emphasis on the combination of quality and cost measures, and that was often not the case many years ago when these arrangements where first put in place," he says. "Another difference now is that the payer, whether CMS or private payer, and the provider work more closely over time to ensure that the contract is performing as expected and members' needs are being met."

David Sheehy, partner at Accenture responsible for global strategy practice for the life-sciences industry group, says today's managed care models are focused on reimbursement.

networks are the new normal, and pharma companies have to recognize them as customers and allocate the right type of resources for this customer.

DAVID SHEEHY / Accenture



In the next three to five years, the industry is going to be impacted by how we influence the end consumer of products. And this influence is changing dramatically with each new entrant into the mix. "

KIM RAMKO / E&Y

"When outcomes and targets in care, quality, and cost become the focus, we will start to have a potential material change in how care is delivered," he says. "Today's predominant model tends to be focused on dealing with a sick patient. With ACOs, we're going to see more of a focus around prevention and wellness and a similar shift from managing around a care setting or episode to an ongoing approach to managing care. There will be a similar shift from dealing with a patient in an office or hospital setting to dealing with a patient in the home with mobile health approach to support the patient."

Dr. Fera says the biggest difference between managed care and ACOs is the clinical information that will be available to providers and the embedding of quality measures into the reimbursement model.

"Managed care became a monetary construct that was all about financial capitation," he says. "It wasn't managing care; it was managing dollars. Unfortunately, that's how it evolved because that was the only thing people could measure. What couldn't be measured were the quality processes that were being followed or the outcomes that patients experienced. What we have now is a safeguard by incorporating quality measures and balancing the financial aspects. This big difference is the ability to gather and report on clinical information. The fear that capitation will cause doctors to withhold care is gone now because we are not only measuring

the cost of care, but also quality, appropriateness and hence the value of care."

Industry experts say because of a focus on outcomes and shared savings, the ACO concept is likely to spill into the commercial market.

"My sense is employers will like the increased accountability that comes with the ACO concept," Mr. Sheehy says. "Many employers are frustrated with the high level of costs that they and their employees have with healthcare that is not tied to overall improvement in patient health and outcomes. The greater accountability in an ACO will be attractive to an employer."

Dr. Fera says employers are demanding these kinds of activities from payers.

"They want disease programs, case management, partnering with providers, and pay-forperformance programs," he says. "This trend, which has existed for the last 10 years now, will accelerate with accountable care models."

Mr. Hollis says as ACOs become more effective, assemble their network of providers, and develop protocols and health IT infrastructure, they will be more willing to offer that model to the commercial market as well.

"We're seeing big growth on the commer-

cial side," he says. "Every week we're hearing about a new collaborative ACO-like arrangement on the commercial side. There is also the potential for Medicaid ACOs."

Dr. Sarran points out everyone who is paying for healthcare right now - the federal government, state governments, employers, and policyholders — is concerned about what has been an unsustainable growth in healthcare costs.

"As a key player in this space, we are working with providers, including CMS, and are committed to moderating these cost increases and improve quality for our members," he says.

Drug Benefits in ACOs

Currently, only Medicare Part A (hospital coverage) and Part B (medical insurance) would be impacted under the ACO legislation. Medicare Part D (drug coverage) is not addressed within the ACO legislation. Industry experts say it's likely ACOs will establish their own hospital-based formularies for Part A and Part B drugs.

"For Medicare D drugs, I wouldn't expect a change in formulary contracting," Mr. Hollis says. "If anything, we'll probably see higher use of these products. With the exclusion of Part D drugs from the CMS subsidy calculation, providers will be financially incentivized to prescribe oral or self-injectable medications that are focused on preventive efforts, which ultimately keep patients out of the hospital. This could have a negative impact on the prescribing of physician-administered products or hospital-infused Part B products that do count against the subsidy."

But Ms. Howell says there are a lot of people in Washington voicing concerns that excluding the Part D retail pharmacy benefit doesn't make sense.

"Some of the most cost-effective treatment options are often those offered through pharmacy benefit plans," she says. "We need this holistic view of all costs the patient is incurring. I would not be surprised if this became part of future regulations related to accountable care organizations. Some of the larger group purchasing organizations have been pretty vocal about how important it is to have all costs included."

But if ACOs move into the commercial sector, Dr. Fera says the provider and payer together would likely set a formulary.

"In the future, we're going to see device and pharma manufacturers playing a larger role in those discussions, which they need to do if they want to be relevant," he says.

Role for Pharma

As healthcare reform evolves, it will be important for pharmaceutical companies to real-

ACA and Post-Election Reform

With the Affordable Care Act (ACA) set to go into effect in 2014, voters are looking for pharmaceutical companies to be engaged in the reform process, playing an active role in improving healthcare. New research from WG Consulting, a division of ghg,

reveals three-quarters of voters think it's extremely important for the pharmaceutical industry to be involved in controlling/reducing drug costs. In addition, almost two-thirds place the highest importance on pharma manufacturers working more closely with doctors to improve patients' health outcomes, and more than half feel strongly that pharma should provide more patient assistance programs for those in financial need. Almost half place importance on pharma serving as an advocate to expand patient access to drugs.

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strongly that

"In earlier research we performed participate in improving healthwith physicians, payers, and pharma care," says Lynn companies, respondents were split O'Connor Vos. 50/50 on whether it's pharma's job to help with ACA implementation and healthcare reforms," says Lynn O'Connor Vos, CEO of ghg."In contrast, consumers feel strongly that pharma has a key role to play, with communications being one of the primary ways they'd like to see pharmaceutical companies participate in improving healthcare.

"More than 80% think it's extremely or somewhat important for pharmaceutical companies to produce educational materials on healthcare reforms for consumers, as well as to create websites and literature for patients on their conditions and treatment options. In addition, three-quarters put importance on providing apps to help sufferers better manage their conditions. Our research shows a clear call-to-action for pharma to be part of the healthcare solution —

Source: WG Consulting, part of the ghg network

not only in developing treatment innovations but in providing information, guidance and support."

According to the WG research, most U.S. voters remain pessimistic about healthcare. Three out of four expect that the cost and quality of care, access

> to medications and doctors, availability of treatment innovations, and insurance costs and coverage will stay the same or get worse. Those who voted for Mitt Romney are more likely than Barack Obama supporters to believe they will see the overall quality of healthcare decline when the ACA is implemented.

> In contrast, the uninsured are most optimistic about the ACA, with one in three expecting an improvement in the quality of care, compared with just one in five insured voters. In addition, more than twice as many uninsured voters as insured voters think they will be better off in terms of insurance coverage and costs, as a result of the ACA.

"Voters are divided on many aspects of the ACA, with cost of care an issue where we see particularly wide gaps

among segments," says Claire Gillis, CEO of WG Consulting."Almost half of Obama voters believe the election results will leave them better off in terms of cost of care, while just 6% of Romney supporters would agree with that positive outlook. In addition, twice as many African American and Hispanic voters as white voters think they will see improvements on cost of care, with President Obama returning to the White House. There also are major differences among age groups, with 39% of voters under 35 anticipating cost of care will get better — a view shared by just 19% of those 50 and older."

The WG Consulting research was part of the 2012 Penn Schoen Berland National Post-Election Study. The online study was conducted among 1,202 American voters on Nov. 9 and 10, 2012.

ize that the next three to five years will be a time of change, experts say. Success in this new healthcare model will be dependent upon how companies adapt to and meet the changing

"Business is going to be very much dependent upon how companies can influence the end consumer of products," says Kim

Ramko, America's life sciences advisory leader at E&Y. "This influence is changing dramatically with each new entrant into the mix. ACOs are yet another player that companies need to figure how to collaborate with and be a supplier to."

Mr. Sheehy says in this new healthcare model, pharma companies need to rethink



Wedical groups are typically formed with the intention of improving leverage in negotiations with health plan contracts, whereas the intent of ACOs is to improve the quality of care being delivered to patients through a more coordinated effort.

KENT ROGERS / Acorda Therapeutics



44 As providers transition to accountable care, they will be paid to manage not only individuals but also populations. This lends itself to a different kind of practice paradigm.

DR. BILL FERA / E&Y

how they provide value to healthcare organizations.

"This is going to take pharma companies out of their comfort zone," he says. "Pharma will need to think and behave differently from how they do today. In this model, they can't be perceived as 'pushing products' without thinking about their customers' goals of managing to specific care, quality, and financial outcomes. They'll need to move from a transactional model to a partnership model."

Mr. Sheehy says the traditional salesforce driven model may be less successful as ACOs more tightly manage access to their physicians and their formularies.

"Pharma companies need to think about creating a relationship more at the institution or entity level," he says. "There is a fair amount of change required on the pharma side to help deliver on and help ACOs be successful in their model."

Mr. Rogers points out the growth of ACOs may provide yet another impetus for reducing the enormous sales teams employed in previous decades by pharma

"The new customer-facing teams may be a hybrid between managed markets and sales, a commercial infrastructure that is designed to adapt to what the new environment is going to look like," he says. "There will be more specialized field teams calling on fewer physicians, and these individuals will need to have the technical capabilities and knowledge to detail medical products and devices, but they'll also need business acumen to navigate the complexities of a more administrative organization."

Ms. Howell says it's important for pharma companies to begin the conversation with ACOs and even establish pilot programs around outcomes to support these new healthcare models.

"Sometimes the program is around a very specific or challenging disease state from a cost perspective," she says. "This is a way to put a little risk into the game and be able to look at what is the most cost-effective way to be able to serve a patient population."

Ms. Ramko says pharma companies are going to need to collaborate with ACOs to get more and improved patient data.

"At the heart of the ACOs is true data management," she says. "Electronic medical records are becoming standardized. These standards are providing a framework for ACOs to provide better, more accurate, and deeper data than we've had around patients. If the ACOs can begin to capture more behavioral information, this will allow pharma companies to have a little more insight into how they can better educate and influence patients. Companies struggle every day with patient adherence, and if they can figure out how to influence those behaviors the better off patients will be."

But pharmaceutical companies may have a

tough time convincing ACOs they can provide value in this new model.

Dr. Sarran says his organization typically doesn't develop relationships with pharmaceutical companies.

"We understand that pharmaceutical companies are in business to sell pharmaceuticals," he says. "That's not a judgment. Our work in the accountable care space includes an emphasis on evidence-based care and on managing a population to a set of general costs and quality outcomes. This will typically include a focus by providers on cost-effective prescribing, which may well be in conflict with pharmaceutical companies, which by definition want to sell their products."

Ms. Ramko suggests pharma companies stress to ACOs they are not trying to develop another channel to market a product.

"They need to focus on 'collective intent,' meaning that each person or party has a role to play, and everybody, including pharma, has a contribution to make," she says.

Mr. Hollis says both the ACO and a pharma company have similar goals: to drive adherence.

"At the end of the day, there are a lot of similarities in terms of goals," he says. "Manufacturers can work with ACOs in that realm. There could be some sort of adherence arrangement or disease management contract that both parties would find beneficial."

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