The Drive to High-Value Health: Are ACOs the Answer?
INTRODUCTION

Healthcare reform’s needle in the haystack quickly became the elephant in the room when 7 pages of content recently exploded into over 400 pages of proposed regulation. Welcome to accountable care organizations (ACOs). President Barack Obama signed the Patient Protection and Affordable Care Act (commonly known as the Affordable Care Act [ACA]) into law in March 2010. In an effort to lower future healthcare expenditures and improve the coordination and quality of care, section 3022 of the law calls on the Department of Health and Human Services (HHS) to form the Medicare Shared Savings Program (MSSP). This new program serves as a vehicle for ACOs, an emerging healthcare delivery model, which offers financial incentives to Medicare providers of services and supplies for integrated care.

An ACO is a network of healthcare providers and/or hospitals that furnishes services and supplies to a patient population; this group shares the responsibility for coordinating quality care to the patients in the network. On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS) released its proposed rule on ACOs; the comment period for the rule will last until June 6, 2011. Per the ACA, CMS is set to launch the MSSP by January 1, 2012. While providers participating in ACOs will continue to receive traditional, fee-for-service (FFS)-based Medicare Part A and Part B payments for services and supplies, they may also be eligible to receive additional payments (often referred to as bonuses). ACOs will qualify for such bonuses if they meet certain program savings benchmarks and quality measures set forth by CMS.

Outside the context of Medicare, the trend toward coordinated care for patient populations and the concept of shared savings between payers and provider networks have recently gained momentum. Some groups of physicians, hospitals, and health plans have already formed ACOs or have shown interest in doing so. In a January 2011 survey conducted by Xcenda’s payer market research platform, Managed Care Network (MCN), results showed 58% of the surveyed payers were either already contracting with ACOs or planning to contract with ACOs within the next year.

With the formation of ACOs, payers and providers are forging an important new healthcare delivery model and testing more quality-based reimbursement mechanisms. The emergence of ACOs across the payer landscape and their focus on increased quality and decreased costs require manufacturers to understand how ACOs will impact all stakeholders.

This white paper aims to address the future implications for various ACO stakeholders: manufacturers, providers, payers, and patients. We will examine major changes in role responsibilities and evaluate the challenges and opportunities for each stakeholder group as Medicare launches the MSSP, and various members of the healthcare community test, and potentially transition to the ACO model.
THE FORMATION OF ACOs

To understand the impact of ACOs, one must comprehend the general mechanics of these new legal entities. This section provides the proposed Medicare landscape for ACOs looking to participate in the MSSP. Both the ACA and the CMS proposed rule on ACOs offer guidance regarding the formation of legal ACO entities. Such entities are formed by healthcare providers who agree to assume the responsibility for the overall care, cost, and quality of patients’ care. Eligible ACOs may apply to participate in the MSSP; applications are proposed to be opened annually beginning January 1, 2012.

Per the provisions of the ACA, groups that are eligible to form ACOs include:

1. Physicians and other professionals (including physicians’ assistants, nurse practitioners, and clinical nurse specialists) in group practice settings;
2. Networks of individual physicians and other professionals;
3. Partnerships/joint ventures between hospitals and physicians/professionals;
4. Hospitals employing physicians and other professionals; and
5. Other groups that the HHS Secretary deems appropriate.

CMS also proposes that additional organizations such as Critical Access Hospitals (CAHs) should be able to form or join other ACOs. Furthermore, CMS proposes that Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) should be eligible to join ACOs as participants. The proposed rule from CMS invites public comments on whether FQHCs and RHCs should be able to form their own ACOs.

To participate in the MSSP, CMS proposes that ACOs should have a governing body in place composed of the following:

<table>
<thead>
<tr>
<th>Role</th>
<th>Description</th>
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<tbody>
<tr>
<td>Head of Operations</td>
<td>Would influence or direct clinical practices to improve efficiency and outcomes; the governing body has the ability to appoint and remove the head of operations</td>
</tr>
<tr>
<td>Medical Director</td>
<td>Oversees and is responsible for clinical management; must be a board-certified, state-licensed physician physically in the ACO’s state</td>
</tr>
<tr>
<td>ACO Participants and ACO Providers/Suppliers</td>
<td>Hospital and physician partners within the ACO that have a meaningful financial or human commitment to clinical integration program</td>
</tr>
<tr>
<td>Quality Assurance and Process Improvement Committee</td>
<td>Will be physician-directed to oversee quality and processes of the ACO</td>
</tr>
<tr>
<td>Medicare Beneficiary</td>
<td>ACOs must have the direct governance of at least one Medicare beneficiary</td>
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</table>
In addition to establishing a governing body, the proposed rule indicates that qualifying ACOs must meet the following criteria:

- Demonstrate their abilities in developing and implementing evidence-based medicine (including clinical guidelines and processes); and
- Establish infrastructure that collects, evaluates, and communicates data across the ACO; and
- Demonstrate a formal legal mechanism to receive and distribute the shared savings; and
- Employ enough primary care professionals to serve at least 5,000 Medicare beneficiaries for an assigned period of time; and
- Have defined processes for the following:
  1. Promoting evidence-based medicine
  2. Encouraging patient engagement
  3. Reporting on quality- and cost-related measures
  4. Coordinating care
- Demonstrate patient-centeredness by meeting these following eight criteria:

Per the proposed rule, eligible ACOs with these required clinical and administrative mechanisms in place to support the assigned beneficiaries may apply to enter into a 3-year agreement with CMS.
PAYMENT TO ACOS

Within its current FFS framework, Medicare reimburses covered services on an individual procedure basis. This reimbursement methodology may incentivize providers to perform certain services at higher volumes to receive greater payments. To promote more efficient patient care, CMS is realigning financial incentives to award collaboration between hospitals, physicians, and other specialists.

As previously mentioned, ACOs participating in the MSSP will continue to receive Medicare payments for covered services. In addition, ACOs that meet a savings benchmark will receive a portion of the savings as additional payment. The ACO-specific benchmark rate is calculated based on the three most recent years of claims data for beneficiaries who would most likely be enrolled in the ACO. CMS will use claims data to compute this measure by identifying beneficiaries who received a plurality of services from the ACO’s primary care physicians during the three most recent years.

CMS favors this retrospective beneficiary assignment method to determine eligibility for shared savings for two reasons. First, patient populations change from year to year, and a prospective assignment method would require many year-end adjustments. Second, a prospective assignment might incentivize ACOs to focus exclusively on the patient population considered for the MSSP, which would be in direct contrast with the MSSP’s goal of improving quality of care for all beneficiaries, not only those participating in the program. The following section describes CMS’ proposed plan to distribute shared savings to ACOs.

DISTRIBUTION OF SHARED SAVINGS TO ACOS

In the ACO proposed rule, CMS seeks comments from the public regarding two possible models to distribute the shared savings: one-sided or two-sided distribution models. The two models provide different types of risk-sharing options for ACOs. The proposed one-sided model would allow CMS to share program savings (but not losses) for the initial two years of program participation with eligible ACOs. During the third year of the initial agreement, ACOs that chose the one-sided model would automatically convert to the two-sided model.

The two-sided payment distribution model allows ACOs to share in the savings; however, they are also responsible for incurring any losses annually during the 3-year program participation if they do not meet or exceed their savings benchmark. The savings payments will be paid out to ACOs as a percentage of the difference between the average per-beneficiary expenditure and the expenditure benchmark. Depending on the final payment model chosen, ACOs may share up to 50% of the savings under the one-sided model and up to 60% under the two-sided model, thereby providing an incentive for ACOs to choose the two-sided model at inception and take on the additional risk.

QUALITY PERFORMANCE COMPONENT OF SHARED SAVINGS PAYMENT

Shared savings payments are also contingent on ACOs meeting the Quality Performance Standard. To do so, ACOs must completely and accurately report on 65 quality measures concerning the following five areas:

1) Patient/Caregiver Experience
2) Patient Care Coordination
3) Patient Safety
4) Preventive Care
5) At-risk Population/Frail Elderly Health

Future quality measures are expected to either come from existing quality programs from CMS or by endorsements from the National Quality Forum (NQF). We will explore the opportunities and challenges regarding quality measure reporting under the Provider discussion section of this paper.
In the first year of program participation, ACOs that fully capture and report data on the 65 measures will be eligible to receive 100% of potential bonuses. Reporting this data will allow CMS to set a quality performance benchmark and a minimum attainment level for each measure. Both the performance benchmark and minimum attainment level will be determined prior to the start of each annual cycle. For subsequent years, CMS will use actual ACO performance data to update benchmark levels, and shared savings payouts will be based on meeting actual benchmarks for the individual measures and based on the performance benchmark percentile. For example, if an ACO is at the 90th percentile of its data reporting benchmark, the organization would then receive 90% of its maximum shared savings amount. CMS will assign a minimum benchmark requirement across all ACOs. Failure to meet the minimum attainment level may lead to the ACO’s disqualification from receiving shared savings for the year and termination from the program.

Both the one- and two-sided models weigh the five quality measure categories equally. The following table lists the characteristics for each risk-sharing model:

<table>
<thead>
<tr>
<th>Design Element</th>
<th>One-Sided Model</th>
<th>Two-Sided Model</th>
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<tbody>
<tr>
<td>Sharing Rate</td>
<td>Up to 50% based on quality performance</td>
<td>Up to 60% based on quality performance</td>
</tr>
<tr>
<td>FQHC/RHC Participation Incentives</td>
<td>Up to 2.5% additional shared savings (added to the 50% above)</td>
<td>Up to 5% additional shared savings (added to the 60% above)</td>
</tr>
<tr>
<td>Maximum Sharing Rate</td>
<td>52.5%</td>
<td>65%</td>
</tr>
<tr>
<td>Minimum Savings Rate (MSR)</td>
<td>Varies by population⁵</td>
<td>Flat 2% regardless of size</td>
</tr>
<tr>
<td>Minimum Loss Rate</td>
<td>None</td>
<td>Flat 2% regardless of size</td>
</tr>
<tr>
<td>Maximum Sharing Cap</td>
<td>Payment capped at 7.5% of ACO’s benchmark</td>
<td>Payment capped at 10% of ACO’s benchmark</td>
</tr>
<tr>
<td>Shared Savings</td>
<td>Savings shared once MSR is exceeded; unless exempted, share in savings net of a 2% threshold; up to 52.5% of net savings up to cap</td>
<td>Savings shared once MSR is exceeded; up to 65% of gross savings up to cap</td>
</tr>
</tbody>
</table>

CMS proposes that each ACO must apply an annual 25% withholding rate on its earned performance payments to repay Medicare in case the organization incurs losses. Each ACO must initially demonstrate its financial feasibility to repay losses and cover its downside risk, such as obtaining reinsurance, placing ACO funds in an escrow account, obtaining a surety bond, or establishing a line of credit. ACOs that experience shared losses must submit payment in full to CMS within 30 days of notification. An ACO that experiences a net loss during its first 3-year arrangement period may not reapply to the MSSP.

**SHARED SAVINGS CALCULATION**

As indicated previously, under CMS’ proposed payment structure, one-sided ACOs would be eligible to achieve up to 50% of total savings, and two-sided ACOs would be eligible to achieve up to 60% of total savings. Before these shared savings are calculated, CMS applies several threshold percentages to the total savings (as illustrated in the tables below). Once the final savings are computed, CMS applies a payment cap and withholds a percentage of the final savings before the ACO may distribute the payments to its participating providers. The following tables provide examples of the payment flow within the one-sided and two-sided ACO models and encompass the metrics listed in the table from the previous section⁶.
The reimbursement methodology under the MSSP places financial accountability and risk on the provider organizations. This reimbursement model aims to avoid reducing costs and services at the expense of quality care. It is also expected to foster increased communication and coordination between providers regarding patient care decisions. In turn, care efficiencies and quality are expected to increase. The increased levels of patient care coordination will likely decrease instances of preventable complications and avoidable hospitalizations. In the next section, this paper will provide a further examination of ACOs’ potential impact, challenges, and opportunities for manufacturers, providers, payers, and patients.
IMPACT ON HEALTHCARE STAKEHOLDERS

Various stakeholders throughout the entire healthcare system will feel the ripple effects of MSSP implementation and ACO growth. Providers may experience the deepest impact, but private payers and patients will also notice changes throughout the delivery of care. Pharmaceutical manufacturers must closely monitor providers, payers, and patients during ACO implementation and anticipate their reactions and changing relationships with each other. It is vital for each stakeholder to weigh the opportunities and challenges of interacting with ACOs, and then develop a strategic plan for the future.

PHARMACEUTICAL MANUFACTURERS

Pharmaceutical manufacturers will experience secondary, albeit high-gravity, side effects from ACO implementation. As the healthcare focus turns from volume of care to quality of care, manufacturers may find value in examining each of their products and therapies under a microscope. Transparency combined with compelling clinical and health economic outcomes data may provide advantages for manufacturers when interacting with providers throughout the healthcare spectrum.

Opportunities for Pharmaceutical Manufacturers

Electronic Health Records (EHRs)

As a prerequisite for ACOs, EHRs will help illustrate the real-world impact of drugs on quality of care by channeling empirical evidence to providers. By demonstrating how their products improve clinical outcomes for patients in retrospective EHR-based studies, manufacturers may be able to distinguish themselves from competitors and find a much more receptive institutional audience. EHRs allow providers to see and evaluate each patient's health risks, health behaviors, and overall health status before they walk into the examination room. Transparency in one sector encourages transparency in affiliated sectors; therefore, manufacturers will likely maintain ongoing relationships with providers by conveying each product's added value for patients.⁷

CMS requires each ACO to achieve “meaningful use” of EHRs from an early starting point. At least 50% of an ACO’s primary care physicians must utilize certified EHR technology to continue participating in the MSSP. CMS plans to terminate any ACO arrangement if fewer than 50% of its primary care physicians are not meaningful EHR users by the organization’s second performance year.⁸ The following table lists the three key components of meaningful use, as specified by the American Recovery and Reinvestment Act of 2009 (ARRA):⁸

<table>
<thead>
<tr>
<th>Meaningful Use of EHR</th>
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<tbody>
<tr>
<td>1. Use of a certified EHR in a meaningful manner, such as e-prescribing</td>
</tr>
<tr>
<td>2. Use of certified EHR technology for electronic exchange of health information to improve quality of healthcare</td>
</tr>
<tr>
<td>3. Use of certified EHR technology to submit clinical quality and other measures</td>
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</table>

Since each ACO’s contract with the MSSP is partially contingent upon meaningful use of EHR, participating providers may feel added pressure to thoroughly and correctly utilize certified technology during the organization’s first few performance years. With EHRs becoming commonplace within ACOs, participating providers may grow more sophisticated in their ability to track outcomes in their patient populations. Tracking outcomes will likely lead to providers changing their behaviors according to EHR-based outcomes studies. Coupling this type of data with clinical trial data may become a prerequisite to an effective physician detail. Once ACOs are more fully implemented, manufacturers will likely notice a strong correlation between high-quality health outcomes of particular drugs and provider prescribing behavior.
Formulary Influence

CMS requires ACOs to report on numerous quality measures that correspond with delivery of care. When negotiating with ACOs and vying for inclusion into their formularies and treatment guidelines, manufacturers may find greater success by providing economic or outcomes-based data that supports the organization’s goals, especially for value-priced preventive medicines and companion diagnostics. Outcomes-based data that may support an ACO’s goals include clinical evidence that the manufacturer’s therapy reduces comorbidities, prevents hospital admissions and longer lengths of stay, minimizes side effects that lead to extended care, and requires a lower number of physician administrations. Demonstrating a lower total annual cost of care for a patient population receiving one medical intervention versus another may carry more weight when compared to the siloed mentality that can exist between outpatient services and inpatient services.

Collaboration with ACOs

If an ACO believes a manufacturer’s products will support its quality of care and cost savings goals, the organization may offer manufacturer representatives the opportunity to join the ACO in an advisory role. An ACO may encourage representatives to provide education to its primary care physicians and other participating providers about the appropriate use of the manufacturer’s products within treatment guidelines. Manufacturers and providers may form strong professional relationships by joining services with a collaborative lens on quality improvement. Patients will likely experience the greatest benefits if cost savings and high-quality care remain the primary focus of any stakeholder collaborative.

Challenges for Pharmaceutical Manufacturers

Exclusion of Medicare Part D Expenditures

As mentioned previously, Medicare Part D expenditures are not included in CMS’ calculation for setting each ACO’s benchmark. CMS proposes to take into account all expenditures for Medicare Parts A and B services for assigned Medicare FFS beneficiaries when calculating an ACO’s expenditures to set its benchmark. This calculation will include all Parts A and B claims for Medicare patients, not just the cost of care provided by the ACO. In addition, this calculation includes payments made under a demonstration, pilot program, or time-limited program. CMS will use the payment amount listed on claims, so the computations do not include copayments, deductibles, and coinsurance.

Critics of this provision believe CMS has inadvertently opened a loophole for providers by excluding Medicare Part D expenditures from the benchmark calculation. This exclusion may incentivize an ACO’s participating providers to prescribe Part D drugs because the expenditures will not count toward the ACO’s cost of care, thus leaving more room for shared savings. Furthermore, manufacturers are already burdened by Medicare Part D prescriptions due to ACA’s mandate to gradually close the Medicare Part D coverage gap by requiring manufacturers to provide a 50% discount for brand-name drugs. Manufacturers that only produce physician-administered Medicare Part B drugs may be held hostage by this impending loophole.

Reduced Access to Primary Care Physicians

Primary care medicine is the core element of every ACO because primary care physicians serve as the front-line contact and guide patients through the chain of care by connecting them to other providers and specialties. These physicians will likely limit access to sales representatives as they join larger, busier practices. Many believe physicians’ time spent with each patient will significantly increase under this model, thus further reducing access for manufacturer sales representatives. Physician groups hoping to qualify for ACO status may also reduce access as they devote time
and resources toward installing EHR systems. In addition, ACOs are likely to develop group policies and product recommendations that govern manufacturer access to physicians; consequently, manufacturers may experience challenges in overcoming red tape when trying to schedule one-on-one meetings with physicians. ACO provider teams, armed with therapeutic and cost-benefit expertise, will likely determine formulary and policy guidelines, which may create a communication barrier for manufacturer sales representatives who are not equipped with matching expertise.  

ACOs will likely financially incentivize participating providers to prescribe cost-effective drugs, comply with formularies, and follow ACO-recommended treatment guidelines. By means of shared savings, providers are financially vested to utilize cost-effective treatments and prescribe economical drugs, so manufacturer sales representatives may struggle when trying to influence providers to prescribe products that are not supported by the ACO. Fortunately, manufacturers that prepare appropriately and employ sales representatives who can discuss outcomes and create innovative patient-centric disease programs and evidence-based demonstration projects may experience better access across a larger number of physicians.

**Potential Rise of Generic Drugs**

For inpatient care, ACOs may spark an increase of generic drug usage. As providers strive to increase quality of care and reduce costs, they may begin to pursue lower-cost treatment options. Utilizing generic drugs or lower-cost alternatives may reduce drug expenses for an ACO’s patient population and prevent the need for more expensive therapies. Manufacturers may need to become more concise and sophisticated when marketing their products to providers by assembling a message that promotes the system-wide savings of using their drugs, along with patient outcomes data. ACOs will challenge physicians to balance the benefits of administration costs with the downside of increased overall costs and risk of losing the organization’s contract with the MSSP. It is important for marketers to tweak product messaging to ACO audiences because many believe the spending is now controlled by the system, not the physician.

**PROVIDERS**

Providers are the front-line stakeholders who will likely absorb the direct shockwaves of ACO implementation. Enhanced primary care is the backbone of every ACO, as primary care physicians usually function as the initial patient contact or operate as connectors to other providers. The goal of accountable care is to efficiently coordinate care across different healthcare settings and deliver high-quality output for the lowest possible costs. Successful ACOs will ensure that patients receive care in the most appropriate, least-intensive settings possible, and that care is not duplicated or conflicting.

Proponents of ACOs believe that coordinated, enhanced care will reduce the demand for high-end procedures, specialist services, and unnecessary, duplicative care. Given that the average Medicare beneficiary visits two primary
care physicians and five specialists each year, providers may experience numerous opportunities to coordinate care and improve the overall patient experience. Some believe that primary care physicians will take more control and use less specialist care, primarily because specialists are allowed to join and receive payments from multiple ACOs. By accepting a greater responsibility in their patients’ care, primary care physicians may experience more opportunities to report their delivery of quality care to CMS and reap the financial benefits.

As detailed previously, CMS plans to assess each ACO based on 65 quality measures. Providers can meet most quality measures by establishing and adhering to several systems already in place, including Medicare’s Physician Quality Reporting System (PQRS), EHRs, and e-prescribing. Satisfactory performance within these quality measures and performing under the predetermined expenditure benchmark set by CMS will result in the opportunity for providers to share a portion of the ACO’s savings. CMS will continue to reimburse participating providers on an FFS basis, and the ACO’s potential shared savings will help supplement these payments. The following chart illustrates the payment flow for a physician group practice ACO:
Opportunities for Providers

Shared Savings

Providers participating in ACOs that meet the aforementioned quality measures and incur annual Medicare expenditures below the predetermined benchmark are eligible to receive a portion of the savings they help achieve. The amount of savings is computed by subtracting the organization’s annual Medicare expenditures from a predetermined benchmark set by CMS. This benchmark is based on the Medicare FFS claims data of the ACO’s patient population and acts as an instrument to anticipate the organization’s performance. An ACO is eligible to receive 50% or 60% of these savings, depending on the payment model employed. By incorporating a FQHC or RHC in its organizational arrangement, an ACO is allowed to receive up to 2.5% or 5% additional shared savings, again depending on the payment model. As indicated previously, providers will not be eligible for shared savings if they do not meet CMS’ quality measures, regardless of how much money they save under the expenditure benchmark.

Once shared savings are obtained, an ACO may allocate the funds to its participating providers through several payment methods. Potential payment options include:

<table>
<thead>
<tr>
<th>ACO Payment Structure Options</th>
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<tbody>
<tr>
<td><strong>Shared Savings Bonuses</strong></td>
</tr>
<tr>
<td>• ACO reserves a percentage of shared savings payments for bonus payments to affiliated providers</td>
</tr>
<tr>
<td>• Proposed by MedPAC</td>
</tr>
<tr>
<td>• Low risk level for providers</td>
</tr>
<tr>
<td><strong>Bundled Payments</strong></td>
</tr>
<tr>
<td>• Gives ACO authority to distribute per-episode payments to affiliated providers</td>
</tr>
<tr>
<td>• Proposed by private payers</td>
</tr>
<tr>
<td>• Medium risk level for providers</td>
</tr>
<tr>
<td><strong>Capitated Payments</strong></td>
</tr>
<tr>
<td>• Allows ACO to allocate predetermined, per-patient annual payments among affiliated providers</td>
</tr>
<tr>
<td>• Proposed by private payers and state of Massachusetts</td>
</tr>
<tr>
<td>• High risk level for providers</td>
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Improvement of Patient Experience and Coordination of Care

Providers have indicated that lack of patient information is a rigid barrier when striving to improve coordination of care. The current FFS payment system yields fragmented care that often results in different providers receiving different, disconnected payments. To improve this disconnect of care, CMS has agreed to provide claims data for patients across all providers participating in an ACO. Depending on the timeliness of these data, providers will be able to see the services that other providers in the ACO are delivering, which will allow primary care physicians to serve as more effective care coordinators. The ACO must notify the patient and receive approval before requesting claims information, but the patient will not suffer any negative repercussions for declining.

Beyond improving data transparency, ACOs may focus efforts on lifestyle modification programs and interventions that carry a high return on investment. Such interventions and their potential impact include:

- **Tests and procedures that focus on prevention and early diagnosis, which may lead to higher-quality care and cost reduction**
- **Immunizations, weight management programs, and smoking cessation services, which may prevent certain diseases**
Regular screenings for serious diseases (e.g., cancer and heart disease), which may lead to early diagnosis and prompt treatment

Evidence-based treatment guidelines and shared decision-making tools, which may reduce costs by preventing unnecessary, duplicative, and even potentially harmful tests, procedures, and medications

Although many of these interventions and programs already exist, ACOs may alter the focus to a more effective or routine implementation. ACOs may also stress the importance of case managers and patient educators, as their regular communication with patients will likely play a key role in preventing diseases and unnecessary care. Studies have demonstrated that stronger patient education and access to primary care may reduce emergency room visits and hospitalizations for patients with chronic diseases and ambulatory-sensitive conditions by 20% to 40%.

Physician Engagement

Successful clinical care delivery within an ACO requires strong inter-physician relationships and business-savvy provider leaders. Internal inclusivity and cross-functional synergies may lead to valuable strategic input from participating providers. Hospitals can work with physicians to improve delivery of care by holding leadership roles within an ACO, offering quality incentives, and seeking provider input on IT initiatives. CMS requires providers and other ACO participants to control 75% of the organization’s governing body, meaning participating providers carry a strong voice for shaping the organization’s future and strategic fit. The remaining 25% includes Medicare beneficiary representatives and financiers who contributed capital to support the ACO’s early operations.

Challenges for Providers

Initial investment

CMS projects that the first-year costs to start an ACO are approximately $1.75 million. Participation in an ACO requires providers to invest in healthcare information technology to track patient outcomes and coordinate care with hospitals, physicians, and other healthcare providers. In addition, providers may incur expenses for consulting with attorneys since ACOs must have the ability to legally allow receipt and distribution of shared savings payouts from Medicare. ACOs will also spend money during initial phases to implement a compliance program, produce and distribute marketing material, and restructure internal operations to allow for CMS monitoring and audits.

Critics question the economic sustainability of ACOs and believe that these organizations may lose money during their first few years of operation. The New England Journal of Medicine (NEJM) recently analyzed 10 integrated health systems in CMS’ Physician Group Practice Demonstration (the first pay-for-performance initiative for physicians under the Medicare program) and discovered that the majority of early adopters did not recoup their start-up costs during their first three years of operation. Each integrated health system spent approximately $1.7 million to participate in CMS’ demonstration project. Of the 10 integrated health systems studied by NEJM, two received a shared savings payment in the first year, six received a payment in the second year, and five received a payment in the third year.

Everett Clinic in Washington spent approximately $1 million to develop infrastructure for its ACO but earned only $125,000 in shared savings payments. When asked about the facility’s lopsided performance, James Lee, MD, Everett’s medical director for hospital efficiency, stated, “It was not profitable for us. Everett is already in one of the lower-cost regions. We had to lower costs in comparison to the local market, and that was a challenge. The issue of geography must be addressed.” The authors of the study suggest that the ACO model will become more economically viable if CMS issues bonus payments based on cumulative savings over several years rather than annual payments.
**Downside Risk**

Some providers may feel disinclined to participate in the MSSP due to CMS’ requirement for ACOs to repay any losses that exceed the expenditure benchmark. As detailed in the Payment to ACOs section, ACOs may choose to employ the one-sided risk-sharing model or the two-sided risk-sharing model. The one-sided model does not impose penalties for losses until an ACO’s third performance year, but the two-sided model requires the organization to assume loss liability during its first performance year. Some providers may not welcome the added pressure caused by participating in an organization that CMS financially penalizes for failing to perform under the expenditure benchmark.

**Cap on Shared Savings**

Providers may experience several challenges after they achieve shared savings due to payment caps and withholding rates. As described in the Payment to ACOs section, CMS applies a 7.5% payment cap to one-sided ACOs, and a 10% payment cap to two-sided ACOs, meaning the organization’s savings cannot exceed these percentages of the aggregate benchmark. After the payment cap is applied, CMS withholds an additional 25% of the final savings to cover any risk of the ACO’s inability to repay shared losses in the future. Due to these limits and additional withholdings embedded into the ACO payment calculation, providers may feel less incentivized to strive for additional savings once they hit the payment cap.

**PRIVATE PAYERS**

Medicare has dominated the spotlight recently regarding ACO discussion and development, but private payers have also been implementing ACO pilot programs across the nation to expand services to commercially insured patients. The opportunity for private payers to collaborate with ACOs may provide several possible advantages. Many believe that hospitals and physicians will lead the charge toward high-quality and low-cost care, and private payers will follow. However, this process could occur in the reverse. Private payers may be able to influence hospitals and physicians by interacting with ACOs and modifying their payment methodologies to better suit the needs of policyholders included in the ACO population. Recently, Xcenda surveyed private payers from MCN regarding their involvement in ACO implementation. Xcenda asked 33 private payers about the anticipated benefits and challenges of working with ACOs (respondents were allowed to record more than one answer). The responses indicated:

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**Benefits**

- Reduced administrative burden: 62%
- Reduced liability: 15%
- Too early to tell: 10%
- Aligned incentives: 5%
- Other: 8%

**Challenges**

- Developing payment incentives: 51%
- Determining cost share amounts: 17%
- Patient confusion: 15%
- Finding providers to participate: 10%
- Other: 7%
Some payers are already investigating new models that parallel ACO requirements. For example, UnitedHealthcare (UHC) is testing a payment model designed to deliver better medical outcomes for cancer treatments. Inputs for this payment model include the costs of patients’ cancer care and the portion of chemotherapy drug profits the provider receives. The model calculates the difference between the group’s current fee schedule and the cost of drugs. UHC will continue to reimburse office visits, chemotherapy administration, and lab fees at FFS rates. To prevent conflicts of interest, UHC will disconnect provider income from drug sales revenue by paying the same fee regardless of which drugs the provider administers.\textsuperscript{21}

**Opportunities for Private Payers**

**Collaboration with ACOs**

Private payers will have the opportunity to contract with ACOs to consolidate resources and provider expertise, which will benefit their patient population. ACA has tightened its grip on private payers by implementing mandates that prohibit the pre-existing conditions exclusion, expand benefits, implement minimum medical-loss ratio requirements, and increase pressure to restrain premium increases. Private payers may be able to mitigate some of these new pressures by shifting some risk to an ACO and its larger patient population.

As an example, Blue Shield of California, Catholic Healthcare West, and Hill Physicians formed an ACO to manage 40,000 members of the California Public Employees’ Retirement System. The collaborative set the goal of keeping healthcare costs flat in 2010 by merging the existing Blue Shield HMO benefit product with members affiliated with existing primary care physicians from Hill Physicians. The ACO experienced first-year results of improved care and millions of dollars in savings. In addition, the collaborative did not increase premiums in 2011. Involved stakeholders stated that the biggest challenges stemmed from data creation, sharing, and access.\textsuperscript{22}

**Collaboration with Providers**

Across the nation, providers are approaching private payers to gauge their support of ACO development. Private payers will have the opportunity to offer their input into the process of shaping ACOs. ACOs may develop too quickly and in the opposite direction of private payer goals if payers fail to offer feedback and insights regarding ACO design from an early stage. Costly mid-course adjustments may be needed if this happens; therefore each stakeholder may find value in taking a collaborative, proactive approach instead of adjusting ACO inter-workings down the line.

### Cost-Reduction Measures for Various Stakeholders\textsuperscript{22}

<table>
<thead>
<tr>
<th>Private Payers</th>
<th>Medical Groups</th>
<th>Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Promote a value-based benefit structure</td>
<td>Narrow practice pattern variation</td>
<td>Reduce potentially preventable events</td>
</tr>
<tr>
<td>Implement reference pricing</td>
<td>Monitor adherence to evidence-based medicine</td>
<td>Develop enhanced intensive care units</td>
</tr>
<tr>
<td>Provide narrow networks</td>
<td>Offer chronic care self-management</td>
<td>Establish end-to-end pre- and post-discharge planning</td>
</tr>
<tr>
<td>Adopt detailed prescription drug management</td>
<td>Incorporate email communication, e-visits and mobile apps</td>
<td>Institute extensive EHR functions</td>
</tr>
</tbody>
</table>

Private payers are also expected to begin testing different methods for the best ways to pay ACOs; thus, private payers may actually be able to lead the charge in this respect. Furthermore, some private payers may indirectly become unofficial “ACOs” themselves by utilizing their own networks of participating providers or by leveraging their staff model HMO arrangements. Proponents of ACOs believe that a collaborative discussion with the various participating payers would be an advisable early step in planning an ACO arrangement.
Insurance Exchange Population

Some believe that various providers are forming commercial ACOs in the private sector to seek private payers whose number of policyholders will expand significantly once state-level insurance exchanges are established in 2014.23 Mandated by ACA, insurance exchanges are competitive marketplaces where individuals and small businesses can purchase qualified health benefit plans with various coverage options. Although the CMS-proposed ACOs only serve Medicare beneficiaries, providers can collaborate with private payers to assemble similar organizations, which will help providers get their foot in the door and potentially gain additional business from the impending flood of exchange beneficiaries. The Congressional Budget Office (CBO) projects 24 million people will purchase coverage through the exchanges by 2019.24

Challenges for Private Payers

Uncertainty of Uniform Payment Reform

There are hundreds of private payers and healthcare payment programs in the United States, each of which offer a vast variety of reimbursement policies, payment methodologies, and rates. ACO implementation may motivate private payers to assess their current pay-for-performance measures and compare them to ACO metrics. Proponents of ACOs believe that private payers across the healthcare spectrum may be able to improve care by implementing uniform performance measures and quality standards. In reality, private payers will not likely implement the same types of payment reform.25 One payer may promote and reward the delivery of high-quality care, while others may uphold FFS payments that reward volume.

Regardless of the payment methods that private payers currently employ, they may find value by modernizing and establishing uniformity for certain payment elements. All private payers will not be able to implement completely identical payment systems, but efforts to establish uniformity in smaller quality initiatives that mirror ACOs’ goals may lead to healthy results. For example:10

- **Payment systems should not limit ACOs’ efforts to develop and deliver services that improve quality of care; instead, payment systems should provide funding for these initiatives and encourage innovative ideas.**

- **Payment systems should not correlate all payments with the number of procedures that providers deliver, such as the current FFS payment system. Critics of this system believe it penalizes providers for delivering fewer procedures.**

- **Payment systems should not implement different quality measures for evaluating ACOs. Tracking and assessing different measures for similar patients may be expensive and inefficient, and ACOs may have trouble detecting changes in outcomes if quality measures are collected for only subsets of patients.**

By implementing these ideas and establishing uniformity in smaller quality initiatives, participating patients will likely notice aligned and improved care. The following graphic illustrates this transition:10
**Shift of Market Power**

Although many argue that providers reclaiming a portion of market power from private payers will breed healthy results, some private payers are concerned that the financial incentives and enhanced collaboration between physicians and hospitals within a geographic area may instead increase the market power of providers and result in higher costs to payers. By encompassing a large patient population, ACOs may indirectly dictate the coverage policies and treatment guidelines of private payers because they must strive to deliver care within certain quality parameters. ACOs and private payers may disagree over coverage if private payers do not cover, or only partially cover, certain procedures that ACOs need to deliver for quality of care reporting purposes.

**No Guarantee ACOs Will Succeed**

CMS has the authority to terminate an ACO’s contract if the organization does not achieve satisfactory scores on quality of care requirements. This unknown element provides significant risks for private payers hoping to collaborate with an ACO because they cannot participate in the organization’s governance structure. Only the organization’s participating providers can determine its future. Private payers may want to avoid vesting too deeply within an ACO because the organization could perform poorly, lose its contract with CMS, and systemically unravel, along with every affiliated stakeholder. To mitigate this risk, private payers may find value in diversifying their sources of policyholders and not relying too heavily on multiple ACOs for their books of business. Private payers can take the proactive approach by researching the overall patient satisfaction of an ACO’s participating providers before deciding to collaborate with the organization.
**Patients**

An ACO’s primary function is to foster strong patient-provider relationships that promote collaborative and responsible healthcare decisions. Because ACOs are patient-centered organizations, CMS requires participating providers to notify their patients about any affiliation with an ACO. Participating providers must inform patients that they are eligible for shared savings payments because the ACO offers financial incentives to improve quality of care and reduce costs. Furthermore, participating providers must alert their patients that the ACO is financially bound to its performance and must pay penalties to CMS for failing to provide high-quality and cost-effective care. Patients are free to seek care from non-ACO affiliated providers at any time.

CMS requires participating providers to notify their patients that the ACO may use and share the patients’ claims data throughout the organization. Although the availability of claims data may improve the coordination of patient care, the provider may not require any patient to obtain services from other providers within the same ACO.

**Opportunities for Patients**

As primary care physicians are expected to take a greater role in coordinating patient care and prescribing preventive care, the trend toward ACOs may translate to improved overall healthcare for patients. Furthermore, patients will have the freedom to select their providers, and may choose physicians who are part of high-performing ACOs. As a result, the patients’ selection process will create competition among community ACOs to provide quality care while maintaining savings goals. Practically speaking, patients may pay less for higher-quality care under ACOs’ care.

In addition, Medicare beneficiaries are built-in components of the ACO governance structure per CMS’ proposed rule. Participation within an ACO’s governance may present greater opportunities for patients to advocate for themselves and play vital roles within community ACOs.

**Challenges for Patients**

On the other hand, the general patient population will likely need education to help them better understand the new ACO landscape. While participating providers must post signs in their facilities and provide written notices to patients about ACO participation, these initiatives may not be enough to help the general patient population understand the new concept of ACOs. Another concern regarding ACOs from the patients’ perspective is that the ACO model may create incentives to limit the use of new, more costly drugs and technologies. Significant precautionary measures must be taken to safeguard patients’ access to appropriate therapies.

**Strategic Recommendations**

To navigate the changes brought on by ACO implementation, manufacturers should first consider education to internal teams (senior executives, research and development departments, brand teams, field-based representatives, etc) on the essential concepts of ACOs and shared savings to ensure all internal teams appreciate the opportunities and risks associated with this new healthcare delivery model. Level-setting internal teams’ knowledge regarding ACOs would provide streamlined future communications regarding strategic and tactical planning for the ACO customer group.
At the same time, conducting an ACO market segmentation analysis could be helpful to manufacturers for purposes of targeting certain groups and for resource planning. As part of the segmentation study, it would be worthwhile for manufacturers to explore the governance structures of major ACOs of which their key provider customers are a part. As mentioned, the ability to influence the formulary decision-making process may be a larger challenge for manufacturers with ACOs in place. Manufacturers may also find it advantageous to have insight into the administrative and clinical structures of key ACOs. By doing this, manufacturers may notice an increase in access to primary care physicians, who will have larger roles in patient care in the ACO landscape.

On a larger scale, manufacturers should also be ready to educate the new ACO stakeholders about the value of their products. Currently, manufacturers demonstrate the clinical and economic value of their marketed products via publications, field tools (such as formulary budget impact models, cost-effectiveness analyses, etc), and value-based messages. These tools and messages, currently developed for the payer audience, may need to be modified for decision makers at the ACO level. The need to incorporate health outcomes data into studies of pipeline products will become increasingly important. Health economics data that address the goals of coordinated quality care and lowered expenditure growth would be immensely valuable for the ACO audience.

Over time, manufacturers could develop a broader view of ACOs for certain geographic regions; manufacturers may become sources of education to individual providers. Information regarding participation in ACOs, MSSP updates, health information technology, and other best practice topics might be helpful, value-added offerings for providers.

**CONCLUSION**

Since the release of CMS’ proposed rule on ACOs, the constructs regarding the implementation of the MSSP have become much more concrete. However, as the MSSP nears launch and other newly created ACOs begin to hit the market, the true impacts on stakeholders still remain to be seen. How will ACOs view and treat branded therapies? In practice, how will patients’ access to drugs actually be affected? What will successful integrated relationships between physician networks, hospitals, and payers look like? The road to improved overall healthcare and lower growth in expenditures may be long with many turns along the way. Whether ACOs are the answer to high-value healthcare remains unclear. However, it is advantageous for manufacturers to understand all the inner workings of the new landscape and play a supportive role to providers, payers, and patients during the ramp-up and implementation period to ensure appropriate access to their products.
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