Toolkit



ACCOUNTABLE CARE ORGANIZATION

LEARNING NETWORK

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PREFACE

Our nation's health care system is at a critical crossroads; unsustainable growth in health care costs poses a serious threat to our national fiscal integrity, as well as to individual's and small businesses' abilities to receive affordable, high-quality health care. The current fee-for-service payment system undermines health care providers' efforts to invest in real clinical transformation, while incentivizing the provision of an ever increasing volume of services. Payers are similarly concerned that current attempts by health care providers to better coordinate care and invest in new health information technology (IT) infrastructure will continue to add to already rapidly growing health care costs.

In an attempt to address this challenge, historic national health care reform legislation was passed in March of 2010. This legislation, among other initiatives, includes the creation of a Medicare Shared Savings program, to be implemented no later than 2012, that allows for Accountable Care Organizations (ACOs) to participate in Medicare. ACOs are being recognized as a promising new payment model that could successfully start to realign our current payment system to better reward improvements in the efficiency of care delivery by supporting health care providers' efforts to improve quality and bend the cost curve with the distribution of shared savings.

Over the past few years a number of organizations committed to higher quality and lower costs have come together ahead of the Medicare Shared Savings program to try and form ACOs in the commercial sector and through Medicare and Medicaid pilot programs. The experiences of these organizations, as well as the research of health care policy experts from across the country, have led to the development of one of the first attempts to lay out succinct guidance for the successful implementation of an ACO – the ACO Toolkit. The following work provides a path forward for the implementation of ACOs across the country. By attempting to walk a fine line between being both specific enough to allow organizations to clearly understand the steps needed to become an ACO, and also staying broad enough to make sure the path put forward for implementation is possible for a diverse range of health care provider groups, this toolkit is designed to be both helpful and applicable to a wide array of health care organizations. There is no one organizational make-up that will predetermine a successful ACO. Rather, we believe success will be determined by leadership and dedication to improving the quality and lowering the cost of health care for a community and by alignment and commitment to the guiding ACO principles described in this work.

We want to acknowledge and express our deep gratitude to John Bertko and and Steve Lieberman for their many contributions to this project, without which this toolkit would not have been possible. In addition to a laser focus on "making this real" for practitioners, John and Steve provided leadership, dedication, and creativity to the substantive roadmap that became our collective thinking about this toolkit. Additionally, we want to express our special appreciation to John and Steve for helping to recruit such a talented group of experts, who, both through their own careers and their efforts on this work, have been instrumental in advancing more accountable care across the country. David Chin, Brett Hickman, Sandy Lutz, Craig McKnight, Timothy Ray, Warren Skea, and David Zielke all made tremendous contributions to help define the best organizational models and governance structures needed for an ACO to be successful. Similarly, David Axene, Dan Dunn, Bela Gorman, Joachim Roski, and Mark Zezza all put in tremendous work to clearly articulate the varying technical features required for an ACO to be truly accountable for its performance.

ACO TOOLKIT

Paul Katz and Bob Power have provided invaluable insights on the type of analytical resources and tools needed for an ACO to meet its goals, and Andrew Krueger and Sue Podbielski made considerable efforts to lay out opportunities for ACOs to truly transform their clinical practice while simultaneously reducing total costs. Finally, Katherine Funk and Chris Janney helped us grapple with the necessary legal issues health care providers need to consider before beginning ACO implementation.

A number of other dedicated individuals spent incalculable hours editing, researching, revising and generally making this publication possible. Specifically, without the tireless efforts of Larry Kocot, Sean McBride, Todd Wintner, Aaron McKethan, Julie Lewis, Peter Basch, Tony Hammond, Kristina Lowell, Niall Brennan, Nadia Nguyen, Erin Weireter, Annalia Glenn, Emily Carnahan, and April Choi, this toolkit would not have come to fruition.

The health care landscape is rapidly changing and ACOs are very much in their infancy. Therefore, this toolkit will be continually updated and supplemented over the coming months and years to ensure it stays relevant and helpful to health care providers as they face new challenges in advancing more accountable care.

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Mark B. McClellan, MD, PhD Director, Engelberg Center for Health Care Reform Leonard D. Schaeffer Chair in Health Policy Studies The Brookings Institution

Elliott S. Fisher, MD, MPH Director, Center for Population Health The Dartmouth Institute for Health Policy and Clinical Practice James W. Squires, MD, Professor Dartmouth Medical School

Part 1

Overview and Key Principles of Accountable Care Organizations Elliott Fisher, Mark McClellan



ACCOUNTABLE CARE ORGANIZATION

PART 1: OVERVIEW AND KEY PRINCIPLES OF ACCOUNTABLE CARE ORGANIZATIONS

The Accountable Care Organization (ACO) Toolkit is designed to serve as a reference guide for those in the health care industry who are interested in learning more about ACOs and how they can prepare to participate – as provider or payer – in moving toward implementation of an ACO. Most ACOs will likely "learn by doing," given that each will face unique circumstances and challenges when implementing this new model for fostering greater accountability and improving value in the health care system. At the same time, a common set of technical and policy issues are likely to arise throughout the implementation process.

This Toolkit provides an overview of the ACO model and its role in the current policy context, highlights the key technical and policy issues that will need to be addressed by virtually all ACOs, and provides guidance on how to overcome some of the key challenges that will face those implementing ACOs. This initial version of the guide will be updated and revised on a regular basis through feedback from provider and payer organizations that are moving forward with implementation of ACOs.

Achieving Better Health and Lower Costs

The U.S. health care system faces unprecedented challenges – rising costs that threaten the affordability of care and fiscal outlook of the U.S. government, and a widening gap between the promise of biomedicine and the reality of care that is often impersonal, inaccessible, unsafe, unreliable, and poorly coordinated.

Proposals to address these problems typically focus on only particular aspects of health care reform. For example, some proposals provide more financial support for certain health professionals because evidence suggests that greater access will reduce complications; others suggest paying more for better processes of care because studies have shown that "evidence-based" care can improve outcomes or lower costs.

The ACO approach builds on these reform efforts that often focus on specific groups of providers, such as the medical home model, or on a discrete episode of care, such as bundled payments. On their own, these other initiatives may help strengthen primary care and improve care coordination, but they do not address the problem of supply-driven cost growth. A comparison of these payment reform models is provided in Appendix 1. The table summarizes the key differences between the ACO model and other payment methods: medical home, bundled payment, partial capitation, and full capitation.

Even though many of the other efforts are helpful elements of health care reform, they are often unlikely to achieve significant and lasting impacts on quality and cost. If we want health care reform to provide better care at a lower cost, we must implement reforms that focus on this goal directly. The core principle of accountable care is aligning payments, benefits, and other health care policies with measurable, meaningful progress in improving health care while lowering costs. Exhibit 1.1 illustrates how accountable care addresses the underlying causes of a poorly coordinated health care delivery system.

Underlying Causes of Poor Performance	Principles of Accountable Care
Lack of clarity about aims, and about whose perspectives are most relevant.	Clear aims: better overall health through higher- quality care and lower costs with a focus on patients.
Providers are fragmented and unable to coordinate care well; providers accept responsibility only for what they directly control.	Establish provider organizations accountable for achieving better results for all of their patients at a lower cost.
Payment system drives fragmentation, rewards unnecessary care, and penalizes care coordination and overall efficiency.	Align financial, regulatory, and professional incentives with the aims of better health through higher-quality care, lower costs.
Inadequate information to support provider and patient confidence about the value of reforms.	Valid, meaningful performance measures that support provider accountability for aims and support informed and confident patient care choices.

EXHIBIT 1.1. KEY PRINCIPLES OF ACCOUNTABLE CARE

Overview of the ACO Model

Accountable care is based on the principles of clear, patient-focused aims (better overall health through higher-quality care and lower costs for patients), provider accountability through transparent performance measures that reflect those aims, and payment reforms that use the measures to align provider support with the aims. Accordingly, ACOs are provider organizations that are directly and meaningfully focused on these aims. They are able to monitor and report their performance in improving health and lowering costs, and are supported by financial and professional incentives that are aligned with achieving better health and lower costs for their patients. In summary, ACOs are:

- Collaborations of primary care professionals and other health service providers, such as other physicians and hospitals;
- Organized around the capacity to improve health outcomes and the quality of care while slowing the growth in overall costs for a population of patients cared for by a welldefined group of primary care professionals; and
- Capable of measuring improvement in performance and receiving payments that increase when such improvements occur.

Delivery Systems

ACO configurations can vary, reflecting the diversity of local health care markets. As such, potential provider configurations include – but are not limited to – individual practice associations, physician hospital organizations, and regional collaborations, as well as integrated delivery systems. They may involve non-traditional health providers such as public health and wellness programs with different payer participants. They also can feature various payment incentives, ranging from "one-sided" shared savings within a fee-for-service environment to an array of limited or substantial capitation arrangements with quality bonuses and "two-sided" risk.

While a broad range of organizational models can be ACOs, most health care organizations today do not meet the core principle of accountability – for health, quality, and costs of care over the full continuum of patient care. Such accountability requires a degree of integration or collaboration among providers that is currently not often found outside of integrated systems; however, technological trends and economic and public health pressures are changing this. As effective medical practices, health information technology, and performance measurement all continue to advance, the potential for providers to take more steps to achieve improvements in overall care and receive better support in doing so also will continue to increase.

Financial Incentives – Shared Savings

The ACO model establishes a spending benchmark based on expected spending. If an ACO can achieve quality targets while slowing spending growth, it receives shared savings from the payers. This model is well aligned with many existing payment reforms, but also offers additional support and accountability to provider organizations to enable them to deliver more efficient, coordinated care. This approach has been implemented in programs like Medicare's Physician Group Practice (PGP) demonstration, which has shown significant improvements in quality and savings for several large group practices.

Because the groups receive a share of the savings beyond a threshold level, steps like care coordination services, wellness programs, and other approaches that achieve better outcomes with less overall resource use result in bonuses to the providers who may be reducing up-front revenue. These steps thus "pay off" and are sustainable in a way that they are not under current reimbursement systems. In addition, the shared savings approach provides an incentive for ACOs to avoid expansions of health care capacity that are an important driver of both regional differences in spending and variations in spending growth and that do not improve health.

Key Design Features

Regardless of specific organizational form, the ACO model has several key design features:

• Local Accountability: ACOs must aim to be accountable to their patients and the community they serve. They should also strive to improve patient health and overall care and reduce costs for their patients and community.

- Legal Structure: ACOs must have a formal legal structure with a governing board responsible for measuring and improving performance.
- Primary Care Focus: ACOs must be established on a strong foundation of primary care to impact care at the patient level. The patient population for which an ACO is accountable must be selected based on patients' use of outpatient evaluation and management services, with primary care given the highest priority.
- Sufficient Size in Patient Populations: ACOs must have a sufficient number of patients to ensure that quality and cost impacts at the patient level can be reliably benchmarked and evaluated.
- Investment in Delivery System
 Improvements: ACOs must implement meaningful and identifiable reforms in care delivery, patient engagement, and other aspects of health care that will credibly improve health and costs.
- Shared Savings: ACOs must offer a realistic and achievable opportunity for providers to share in the savings created from delivering higher-value care. The incentive system must reward providers for delivering efficient care as opposed to the current volume-driven system.
- Performance Measurement: ACOs must participate in ongoing performance measurement that provides meaningful evidence of health and cost impacts. Results must be transparent and accessible by patients.

With greater experience and further technical progress, ACO care improvements are expected to become more sophisticated. Examples include more comprehensive care improvement activities, better performance measures – such as more meaningful outcome measures, including patient experience measures – and payment systems and other incentives that rely more on performance than volume, intensity, or other factors unrelated – or often inversely related – to value.

Better Evidence to Help ACOs Succeed

Given that this is a new model, many activities related to accountable care are still at an early stage. The combination of care delivery and payment reform is significantly different from current practice outside of currently capitated health systems and will require time and effort to implement. Providing better evidence of "best practices" to various types of health care providers, communities, and patient populations will ensure that accountable care achieves its goal as quickly and efficiently as possible. Evaluation and learning activities that enable better technical support for ACO implementation are therefore essential to support the deployment of ACOs.

Overview of the Toolkit

The process of setting up and implementing an ACO will involve a multitude of technical, legal, and analytic challenges. These include issues such as the form and management of the ACO, which specific providers to include and how any shared savings will be distributed among them and participating payers, and significant technical and analytic challenges, such as the calculation of spending benchmarks and the selection of appropriate quality measures.

This Toolkit is meant to serve as a guide for ACOs through these issues and the implementation process. It aims to facilitate the process by identifying the challenges that may arise along the way and highlighting the key decisions and functions that will be critical to the formation and implementation of an ACO. This edition is Version 1.0; the Toolkit will be edited and improved based on lessons learned by early adopters and by those moving in this direction in the months and years ahead. The other sections of this guide include:

Part 2. Organization and Governance

ACOs must have a formal legal structure with a governing board to take steps to improve

care and measure performance. ACOs can be developed from many of the existing organizational models, such as Integrated Delivery Systems (IDSs), Physician Hospital Organizations (PHOs), Independent Practice Associations (IPAs), Multispecialty Group Practices, and Regional Collaboratives, with some models requiring more organizational and operational changes than others. This section discusses these models and includes examples of the governance model and required infrastructure.

Furthermore, this section discusses insights on how ACOs can develop the appropriate blend of providers with the right management structure to redesign health care delivery in order to achieve higher quality care at lower costs. This includes a discussion on which providers are most likely to be essential partners, such as primary care physicians and certain specialists and institutions. It provides examples of a management structure to provide administrative and care coordination support, and the resources to manage the operational functions.

Part 3. Accountability for Performance

ACOs are eligible for financial performance bonuses by achieving measured quality targets and demonstrating real reductions in overall spending growth for a defined population of patients. In this section, we outline the processes involved in the ACO cost-of-care budget development and the financial performance evaluation, including a description of the patient attribution process used to determine the ACO population upon which the budget is based. Furthermore, we provide some insights on how shared-savings may be distributed within an ACO.

In an accountability-payment structure, the financial benefits of achieving cost targets should be contingent on quality metrics being met or exceeded. As such, this section discusses the key components and considerations for implementing a quality measurement program, including selecting a broad range of measures, collecting data, developing a standard set of measures, developing targets, calculating performance results, and validating and reporting measures.

Part 4. ACO Infrastructure

For an ACO to successfully deliver the level of integrated and efficient care that would allow it to achieve shared savings, it must have the appropriate information and resources to effectively carry out care delivery functions and to improve the quality of care. The ACO also must be able to monitor progress, evaluate performance against targets, and take appropriate actions to stav on track. This section provides an overview of the essential information and analytical resources needed to achieve a level of clinical integration that improves quality and reduces costs, focusing on the following key elements: data warehouse and data sources, using disease registries to provide physicians and their care teams with meaningful information, and examples of reports for tracking financial and clinical performance. Factors to be considered in assessing the appropriate level of tools and resources for an ACO also are covered.

Part 5. Health Care Delivery Transformations for Achieving High-Value Health Care

To help achieve the aims of better patient outcomes and satisfaction at lower health care costs, ACOs will need to explore opportunities for savings and care delivery improvements. This section provides examples of demonstrated savings opportunities for ACOs through both public and private reform efforts. ACOs should consider both the short-term and long-term opportunities to qualify for shared savings. In the short term, ACOs should consider interventions that can quickly generate savings and return on investment, such as interventions designed to reduce hospital readmissions or relatively simple interventions that correct inefficiencies in care delivery. ACOs should also consider long-term investments, such as interventions aimed at better managing chronic disease. There are many shared savings opportunities for ACOs. In this section, we discuss a few examples from four key transformation areas: 1) care coordination; 2) population or condition specific treatments; 3) patient engagement in care; and 4) infrastructure and organizational redesign. Furthermore, we discuss how ACOs should also aim to layer reforms so that they build on each other. Multi-faceted reforms that integrate different silos of care, including inpatient services, outpatient services, and patient self-management, have the greatest chance of reducing spending while improving quality.

Lessons learned from successful ACO models will expand this section dramatically in the future.

Section 6. Legal Issues for ACOs

An overview of legal considerations in setting up an ACO is provided in this section. Federal level issues include anti-trust issues, physician selfreferrals (Stark law), anti-kickback law, service reduction, civil monetary penalty law, and tax exemptions, while state issues focus on state antitrust laws, state fraud and abuse laws, false claims acts, government-managed care regulations, and corporate practice of medicine and state insurance laws. **APPENDIX 1: COMPARING ACCOUNTABLE CARE ORGANIZATIONS WITH OTHER PAYMENT REFORMS**

Accountable Care Organization (Shared Savings)	Providers are accountable for total per-capita costs. Does not require patient "lock-in." Reinforced by other reforms that promote coordinated, lower- cost care.	Yes – Provides incentive to focus on disease management. thens primary Can be strengthened directly or by adding medical home or partial capitation payments to primary care physicians.	Fosters Tation among articipating roviders Providers
Primary Care Medical Home	Supports new efforts of primary care physicians to coordinate care, but does not provide accountability for total per-capita costs.	Yes – Changes care delivery model for primary care physicians, allowing for better care coordination and disease management.	No – Specialists, hospitals and other providers are not incentivized to participate in care coordination.
Bundled Payments	Promotes efficiency and care coordination within an episode, but does not provide accountability for total per-capita costs.	Yes/No – Only for bundled payments that result in greater support for primary care physicians.	Yes (for those included in the bundled payment) – Depending on how the payment is structured, it can improve care coordination.
Partial Capitation	By combining FFS and prospective fixed payment, it provides "upfront" payments that can be used to improve infrastructure and process, but provides accountability only for services/ providers. May be viewed as risky by many providers.	Yes – When primary care services are included in a partial capitation model, it can allow for infrastructure and process improve-ment, and a new model for care delivery.	Yes – Strong incentive to coordinate and take other steps to reduce overall costs.
Full Capitation	Provides "upfront" payments for infrastructure and process improvement and makes providers accountable for per- capita costs. Requires patient "lock-in." May be viewed as risky by many providers.	Yes – It gives providers "upfront" payments and changes the care delivery model for primary care physicians.	Yes – Strong incentive to coordinate and take other steps to reduce overall costs.

	Removes payment incentives to increase volume v	Fosters Y accountability for s total per-capita o costs c	L Requires providers s to bear risks for n excess costs d	A Requires "lock- in" of patients to specific providers
Accountable Care Organization (Shared Savings)	és - Incentives are aased on value, not olume.	es – In the form of thared savings based on total per-capita costs.	Jimited risk – While here might be risk- haring in some nodels, the model does not require oroviders to take isks.	Vo – Patients are tssigned based on previous care batterns. There tre incentives to rrovide services vithin participating providers.
Primary Care Medical Home	No – There is no incentive in the medical home to decrease volume.	No – Incentives are not aligned across providers. No global accountability.	No – No risks for providers who continue to increase volume and intensity.	Yes – In order to give providers a PMPM payment, patients must be assigned.
Bundled Payments	No – For payments outside the bundle. There are strong incentives to increase the number of bundles and to shift costs outside the bundle.	No -for payments outside the bundle. No accountability for total per-capita cost.	Yes, within the episode – Providers are given a fixed payment per episode and bear the risk of costs within the episode being higher than the payment.	No – Bundled payments are for a specific duration or procedure and do not require patient "lock- in."
Partial Capitation	Yes – Strong efficiency incentive to the degree that prospective fixed payment is weighted in overall payment.	Yes – Strong efficiency incentive to the degree that prospective fixed payment is weighted in overall payment.	Yes – To the degree that prospective fixed payment is weighted in overall payment.	Likely – Depending on the model, patients might need to be assigned to a primary-care physician.
Full Capitation	Yes – Very strong efficiency incentive.	Yes – Very strong accountability for per- capita cost.	Yes – Providers are responsible for costs that are greater than the payment.	Yes – To calculate appropriate payments, patients must be assigned.

Part 2

Organization and Governance

David Chin, Brett Hickman, Sandy Lutz, Craig McKnight, Timothy Ray, Warren Skea, David Zielke



ACCOUNTABLE CARE ORGANIZATION

PART 2: ORGANIZATION AND GOVERNANCE

ACOs are likely to encompass multiple health care providers, so organizational alignments will be critical for ACOs to better manage care across the full spectrum of services provided to their patients. Momentum towards alignment already exists. Hospitals and other health care providers have frequently formed linkages to strengthen their primary care capabilities, offer new delivery models to communities, innovate care management and delivery programs, recruit new providers, and leverage resources more effectively.

There are many issues potential ACOs will need to consider when assessing alignment options, including who to partner with, how to navigate legal and financial barriers, and how to manage the venture. Achieving success as an ACO may require health care organization executives to understand the various models for better aligning medical practice and how leaders can move an organization toward the goal of providing better care that is more integrated and coordinated.

As many ACOs are still in a formative stage, definitive lessons on how new ACO organizations can or should be structured are lacking. Drawing on experience from other related efforts to better align incentives and the organization of health care providers, this section highlights potential ACO organizational and governance models to help identify core issues and potential solutions.

We first discuss the organizational features of the care delivery system needed to ensure that the right mix of providers is available to support an ACO framework. That is, an ACO needs to have access to an appropriate mix of key providers to ensure that the full spectrum of services can be delivered to their attributed patients, and, in turn, be able to impact patients' health and overall cost. Additionally, providers may need to band together to have enough patients to produce statistically meaningful data on cost and quality. Meaningful measurement of performance on cost and quality is key to achieving accountability and necessary for determining shared savings.

The discussion of organizational models presented in section 2.1 relates integrally to the discussion of provider involvement in ACOs presented in the next section (2.2), and the governance models, leadership, and decision-making presented in the third section (2.3). The governance model can often include entities that provide leadership for the ACO – such as foundations or hospital-physician joint venture corporations – but may not be directly involved in delivering health care. Provider involvement must focus on alignment between any new shared-savings or payment reform arrangements and steps that the ACO will take to achieve measurable improvements in the delivery of care.

We also note that sections on organizational and governance models are intentionally high-level. Building on this initial discussion, subsequent sections will provide more operational detail on key issues, such as assuring an appropriate flow-offunds or organizational capability for performance measurement.

BASIC FUNCTIONS

While some functions of an ACO will vary depending on the organizational and governance model, it is expected that most, if not all, provider entities will need to make arrangements for key capabilities to succeed as an ACO. In many cases, additional administrative processes will be needed to provide the following basic functions and to facilitate effective collaboration:

- Develop a patient care process that crosses service settings;
- Negotiate ACO payment models with payers;
- Develop a methodology for shared savings disbursement;
- Enhance information technology and data analysis infrastructure;

- Build capacity to continually learn and enhance care processes;
- Develop prospective budgets and resource planning; and
- Calculate performance metrics.

Health care organizations should seek arrangements that will take advantage of each participant's resources to efficiently deliver the functions necessary for operating an ACO. For example, a physician group may be able to enhance its health IT capabilities by aligning with a hospital that already has an established, effective health IT infrastructure. Hospitals may find similar synergies in driving quality improvement through evidencebased medicine initiatives initiated by physician leaders.

Given the new level of coordination required in both patient management and administration to achieve greater efficiency in care, prospective ACOs will need to consider the various existing delivery care models that can be adapted to meet their needs.

2.1: ORGANIZATIONAL MODELS

An ACO requires a level of organization and governance that is rooted in formal arrangements, such as contracts between providers who are members and the ACO. In addition, an ACO must have the capacity to improve care, with more than a shared budget as the only element in common. The diversity of local markets requires accommodating multiple ACO models. Nonetheless, all ACO models strive to redesign the delivery of health care to achieve greater value in both quality of outcomes and reduction in total costs. To achieve this objective, an ACO requires an appropriate blend of physicians, physician extenders, care managers, and facilities working together to align incentives, share patient information, and apply evidence-based medicine protocols. The selected approach should ensure greater appropriateness and efficiency in the use of high-cost services and improvement in maintaining beneficiary health.

ACOS will vary in the extent to which key providers and facilities are members of the ACO or, for nonmembers, have formal contractual or informal relations with the ACO.

Today's market includes several types of organizations that can support the types of functions required for an ACO, including the following:

Integrated Delivery Systems. Integrated delivery systems (IDSs) typically involve one or more hospitals and a large group of employed physicians. In some cases, these health care systems can also include an insurance plan, even though they typically contract with multiple health insurers. Eight of the 10 participants in the Medicare Physician Group Practice (PGP) shared-savings demonstration, for example, are identified as belonging to an IDS (see Exhibit 2.1). These systems generally feature aligned financial incentives, relatively advanced health IT infrastructures, including the use of electronic health records (EHRs), and have well-coordinated team-based care. As a fully integrated model, IDSs may already be capable of implementing some of the more advanced payment models under consideration for ACOs, such as accepting partial capitation payments.

Multispecialty Group Practices. Multispecialty group practices typically have strong physician leadership through a committed group of physicians who work closely with each other. They usually do not own a health plan but contract with multiple health plans. Most have highly developed mechanisms for providing coordinated care. Additionally, systems to coordinate care and the related costs may be developed or arranged through another partner. Two multispecialty group practices, Marshfield Clinic and The Everett Clinic, are participating in the Medicare PGP demonstration. Physician-Hospital Organizations. Physician-Hospital Organizations (PHOs) are joint ventures between one or more hospitals and at least one physician entity. PHOs can vary from focusing on contracting with payers to functioning like multispecialty group practices but with an explicit link to one or more hospitals. PHOs with the latter characteristic are more likely to focus on improving the delivery of care to enhance quality and reduce costs. Many PHOs may require stronger management and governance focused on clinical integration and care management in order to succeed as ACOs. The Tucson Medical Center, a pilot site for the Dartmouth-Brookings ACO Collaborative, is an example of a PHO experimenting with the ACO model.¹

Independent Practice Associations. Independent practice associations (IPAs) consist of individual physician practices that work together as a corporation, partnership, professional corporation, or foundation. In many instances, the primary motivation for the formation of an IPA has been for purposes of contracting with health plans in a managed care setting. While financial risk in some managed care contracts may be shared among IPA members, the individual practices typically serve non-HMO clients on a standalone basis, and bill under their individual provider numbers. Stemming from their experiences with capitation over the past decades, many successful IPAs have already evolved into more organized networks of practices that are actively engaged in practice redesign, guality improvement initiatives, and implementation

Participant	Organizational Structure	Part Of Integrated Delivery System?	Includes Academic Medical Center?	Owns Or Owned An HMO?	Not For Profit?	Number Of Providers
Dartmouth-Hitchcock Clinic	Faculty/Community Group Practice	Yes	Yes	Yes	Yes	907
Billings Clinic	Group Practice	Yes	No	No	Yes	232
Geisinger Clinic	Group Practice	Yes	No	Yes	Yes	833
Middlesex Health System	Network Model	Yes	No	No	No	293
Marshfield Clinic	Group Practice	No	No	Yes	Yes	1039
Forsyth Medical Group	Group Practice	Yes	No	Yes	Yes	250
Park Nicollet Clinic	Group Practice	Yes	No	Yes	Yes	648
St. John's Clinic	Group Practice	Yes	No	Yes	Yes	522
The Everett Clinic	Group Practice	No	No	No	No	250
University of Michigan Faculty Group Practice	Faculty Practice	Yes	Yes	Yes	Yes	1,291

EXHIBIT 2.1. PHYSICIAN GROUP PRACTICE DEMONSTRATION PARTICIPANTS: ORGANIZATIONAL CHARACTERISTICS

Note: HMO = Health Maintenance Organization

Source: RTI International, as cited in: Report to Congress. 2006. Physician Group Practice Demonstration: First Evaluation Report. <Available as of July 21, 2010 at https://www.cms.gov/reports/downloads/Leavitt1.pdf>.

MEDICARE DEMONSTRATION PROJECTS

While the Patient Protection and Affordable Care Acts (ACA) may have given an unprecedented push to shared-savings models by incentivizing the creation of ACOs, federal initiatives to create shared-savings projects are hardly new. Two ongoing Medicare demonstrations, the Physician Group Practice (PGP) and Medicare Health Care Quality (MHCQ) demonstrations, already involve mechanisms for providers to receive shared-savings bonus payments when their efforts slow health spending and meet quality targets.

PGP Demonstration. Launched in 2005, this five-year demonstration was designed to test whether care management initiatives, when implemented under a shared-savings payment model, could generate cost savings by reducing avoidable hospital admissions, readmissions, and emergency department visits, while at the same time improving the quality of care for Medicare beneficiaries. The ten PGP sites tend to be tightly integrated with numbers of participating providers that vary from just over 200 to more than 1,000 physicians.

MHCQ Demonstration. Established through Section 646 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, MHCQ builds on the PGP Demonstration by testing a similar payment and quality improvement model in multi-stakeholder organizations that include – but are not limited to – physician groups. After several years of development, two organizations launched the demonstration in January 2010: the Indiana Health Information Exchange and North Carolina Community Care Networks, Inc.

of EHRs. Monarch Healthcare in California is an IPA participating in the Dartmouth-Brookings ACO pilot collaborative that is becoming an ACO. For other IPAs, stronger leadership and clearer governance structures may be required to better coordinate information sharing, track costs, and manage care across most IPA practices.

Regional Collaboratives. Another potential model exists when independent or small provider practices organize to become regional collaboratives. This model may be particularly useful for providers interested in forming an ACO that are located in rural areas. Anti-trust and other policy considerations might limit the scope of regional approaches in many metropolitan areas. Leadership in this model may come from a variety of sources, including providers, medical foundations, non-profit entities, or state government, operating through its Medicaid agency or the Legislature. In these cases, the impetus for forming an ACO may come in conjunction with regional collaboratives implementing initiatives such as health information exchanges or public reporting, which can help small practices share information and better coordinate care. The Medicare Health Care Quality Demonstration (MHCQ) includes two sites that can be considered a regional collaborative.

2.2: ROLES OF INDIVIDUAL PROVIDERS INCLUDED IN THE ACO MODEL

ACO success depends on a variety of providers working more effectively together as a system to provide appropriate, coordinated care for ACO patients. Different providers may play various roles that involve directly providing services to patients, as well as ACO governance and operation. The ACO governance roles and responsibilities are explored in more detail in the next section, but generally include legal, fiscal, and clinical responsibilities. Not all providers serving ACO beneficiaries need to be members of the ACO or involved in its governance. In fact, some ACO members – which could include employed or contracted providers – may not participate in shared savings (or losses). However, providers who have patients attributed to them for the purpose of defining the ACO population can only participate in a single ACO.

ACOs also do not change the underlying characteristics of a patient's insurance coverage. For example, if a patient is enrolled in a preferred provider organization (PPO), the ACO does not impose a "gatekeeper" or a closed provider network, over and above the normal requirements of the insurance benefit. Patients attributed to an ACO will not be limited to seeking care from the participating providers of the ACO. ACOs remain accountable for the total cost and quality of care for their attributed patients, no matter where or what services are provided. This responsibility includes care delivered across the full spectrum of services required for patient's health care needs. Inevitably, some of this care will be delivered by non-ACO providers.

In this section, we discuss the various roles that ACO providers must fulfill, including which providers are most likely to be a part of the ACO governance team, an exclusive ACO provider used for assignment, and/or eligible for shared savings. We also touch upon the potential relationships with providers who are not contractual members of the ACO.

The specific configuration for an ACO is expected to vary depending on the local practice environment, patient needs, and infrastructure required to support providers for services such as IT, analysis, performance improvement, and finance. Exhibit 2.2 summarizes the range of possible provider arrangements.

PROVIDERS TO WHOM PATIENTS ARE ASSIGNED

As a core principle, ACOs must rely on primary care as a foundation for achieving improved care at lower cost. Evaluation and measurement (E&M) services provided by primary care providers (PCPs) are the preferred basis for assigning patients to ACOs.² As such, core ACO providers almost certainly will include primary care providers such as internal medicine, family practice, and pediatric providers.³ They may also include specialists who are likely to have frequent contact with patients, particularly for serious chronic diseases, and handle many primary care services.

In addition to being members exclusively of a single ACO (as discussed in more detail in Part 3), these ACO members would have central responsibility for the overall cost and quality of care for their attributed patients. Patients often regard these providers as their personal physician, and the physicians generally provide the entry or coordination point for referring patients to more specialized treatment on a non-emergent basis. The pattern of referrals from personal physicians is likely to have a critical impact on the overall cost and quality of care received by ACO patients. These "high touch" providers ideally develop longterm relationships with their patients through a combination of regularly scheduled and episodic visits.

Core providers may encounter an increased volume of patient contacts if they assume a larger role in overall care coordination. The widespread consensus that primary care is generally undercompensated may help increase likelihood that PCPs and other core providers will participate in bonus arrangements – either shared savings or losses – as members of an ACO.⁴

Specialists Likely To Have an Ongoing Relationship with Patients

Many providers other than primary care providers also play critical roles in delivering higher-quality and lower-cost care to patients. This category of providers includes those who manage or perform mainly episodic events but with significant resource and quality implications. This group may include physicians in specialties such as cardiology, oncology, urology, neurology, or gastroenterology. Each ACO will need to determine prospectively whether these providers are members and, if so, whether they participate in its governance structure, shared savings, or other programs. For example, these providers might view having preferred referral status or participating in bundled payment arrangements, and accompanying further support to improve patient care, as sufficiently attractive without being eligible for shared savings. Specialists who are members of an ACO may have a role in governance without participating in the shared-savings program.

Other Specialists

Other specialists that typically do not have an ongoing relationship with patients may be members of an ACO, be members of multiple ACOs, or simply not be members of any ACO, but provide services to ACO patients. Examples of such specialties include anesthesiology, radiology, and emergency medicine. In many cases, these providers are less involved in the coordination of care. For greater participation in shared savings, individual ACOs would need to evaluate the circumstances to make a well-informed business decision.

Facilities

Hospitals play a major role in health care delivery, as they provide the most intensive and highest cost care. Their potential inclusion in an ACO should be carefully considered based on several factors, including local market conditions, alignment of interests, leadership in creating an ACO, capital, organizational resources, and patient characteristics. While hospitals are expected to be a key provider for all populations, other entities might be more important in delivering care to specific ACO populations, such as Medicare or Medicaid patients. For example, skilled nursing facilities and home health agencies may play a more important role in serving Medicare patients than commercial patients. Discussions of governance and shared-savings participation should identify clear opportunities for collaboration to improve quality and lower costs.

Non-Contracted Providers

As mentioned above, ACOs are financially accountable for all the care delivered to their attributed patients, whether delivered by ACO members, contracted providers, or non-contracted providers.

Being assigned to an ACO does not change a patient's benefits or access to providers. Therefore, unless ACO patients are enrolled in health plans with prior authorization by PCPs or closed networks – such as HMOs – ACO patients will have some care provided by non-ACO providers. These patients are not locked in to any providers and can receive care from any provider within the insurer network without prior authorization or extra cost. There may also be other reasons to seek treatment from non-contracted ACO providers. For example, ACO patients may seek care from out-of-area providers while traveling. The ACO may have no or very limited ability to influence care from these non-ACO providers.

Other Incentives (e.g., Bundled payments, health IT, Administrative Assistance, preferential referrals, quality bonuses)	Yes	Other factors are expected to be key factor determining ACO participation	Yes	Yes	Q
Shared Savings	These are the providers most likely to be included in shared-savings.	Possible to participate in shared-savings bonuses	°2	Depends on specific circumstances of individual ACOs.	õ
ACO Member or non- Member	Member	Member	Possible member	Possible member	Non-member
Governance Role	These are the providers most likely to Participate in Governance	Possible	Not Likely	If an ACO member, a hospital is likely to be involved in ACO governance	°Z
Assigned Patients	Yes	Not likely	°2	No, Patients are not attributed to facilities.	°Z
Provider Types	e.g., Internal. Medicine and Family Practice, Cardiology (non-interventional), Pediatrics, Pulmonary, Obstetrics and Gynecology	e.g., General Surgery, Hospitalists, Orthopedics, Otolaryngology, Oncology, Urology, Gastroenterology	e.g., Anesthesiology, Radiology, and Emergency medicine	e.g., Hospitals, Skilled Nursing Facilities, and Home Health Agencies	These can be providers out-of-the payer's network (e.g., an out-of-area provider) or providers in the payer's network but who do not routinely work with the ACO providers.
Role in ACO	Core providers (assigned patients if unique to a single ACO)	Specialists more likely to have an ongoing relationship with patients	Other specialists	Facilities	Non-contracted providers

PART 2: ORGANIZATION AND GOVERNANCE | ACO TOOLKIT

EXHIBIT 2.2. TYPES OF PROVIDERS; ROLES AND RESPONSIBILITIES

Organizations with Services in Multiple Categories

There are many organizations or health systems that include more than primary care providers and offer services reflecting some or all of the categories discussed above. For example, multispecialty group practices will often include primary care as well as specialist physicians. To better align incentives and minimize administrative complexity, ACO arrangements with such organizations may prefer to include the full scope of services offered by a group to avoid splitting an existing organization.

One model for creating an ACO would incorporate an entire health care system, making it the basis for the ACO. For example, where an enterprise encompasses both hospitals and physicians, including PCPs, these providers could form an ACO. If sufficiently extensive, the enterprise's network could be the only providers affiliated with the ACO.

2.3: GOVERNANCE MODELS

The success of an ACO may require substantial cultural changes that complement changes in operations. For example, to succeed under the shared-savings model, the business practice of maximizing revenue will need to shift toward a greater focus on efficiency and eliminating unnecessary care. Also, unlike the traditional payer–payee relationship, which gives providers and plans little reason to cooperate, the ACO shared-savings framework rewards coordination and alignment, and may offer the potential to improve relations. Achieving cultural and operational changes will require strong ACO leadership.

Identifying the right leaders is a critical step for enabling an aspiring ACO to succeed. Successful ACOs will require strong, capable clinical, fiscal, and administrative operations leaders. Candidates drawn from existing health system or provider participants may provide a strong group of ACO leaders. Based on their assessment, those leaders may choose to create a free-standing administrative structure to manage and implement the ACO. Alternatively, ACOs may recruit outside candidates as leaders, or choose to implement essential functions by outsourcing services to vendors with proven capability.

ROLES AND RESPONSIBILITIES

The functions of an ACO can generally be divided into two categories – management (administrative) and clinical – which must be implemented together.

Management

Management roles within an ACO include oversight for all strategic and high-level operational issues. Responsibilities may include:

- Oversight of interaction with payers;
- Oversight of coordination with ACO participant and partners;
- Review of data and financial trends; and
- Setting policies for resource distribution including setting criteria of the shared savings and its allocation methodology.

Clinical Roles

The overall clinical role of an ACO is to ensure that the best care is provided in the most economical setting for ACO patients. Clinical responsibilities may include:

- Establishment of care coordination guidelines;
- Review and dissemination of best practice information, including evidence-based guidelines;
- Practice improvement, including identification of providers with outlier practice patterns and strategies for clinical improvement; and
- Handling clinical issues involving ACO patients.

Both roles must be coordinated; for example, performance measures used in ACO financial arrangements should be integrated with clinical strategies to achieve improvements on these measures.

SAMPLE GOVERNANCE MODELS

How ACO management and clinical leadership roles are assigned and organized depends ultimately on the type of organizational model – whether IDS, PHO, multispecialty group practice, IPA, or regional collaborative – as well as the specific infrastructure and market characteristics in play. For example, an IPA model in a rural area with limited infrastructure may look different from a similarly conceived model among suburban physician groups.

Below, we describe two models that illustrate the variety of ACO governance models for entities that include both physicians and hospitals. The Foundation Model might best suit more integrated health systems, while the Clinical Co-Management Model might better suit separate entities interested in forming a virtual organization. These models are by no means exhaustive. Rather than being blueprints, these examples highlight how the degree of integration alters governance considerations, and how governance must promote financial and clinical alignment. The discussion draws on how parties have handled related issues in the past.

Foundation Model

The first approach relates to organizational systems that already exhibit some degree of integrated care delivery. This "foundation model" typically addresses clinical and management issues through two entities:

- The Physician Group. The physician group is fully self-managed and wholly owned by physicians. Physicians in medical groups may be partners or employees.
- 2. **The Medical Foundation.** The foundation is usually established as a tax-exempt 501(c)(3) non-profit public benefit corporation.

The foundation contracts with the physician group(s) through a Professional Services Agreement

"PSA" specifying that the physician group provides professional services to the Foundation's patients. The foundation typically owns and operates the facilities, equipment, and supplies of a practice employing non-physician personnel.

The foundation can serve as a vehicle to make hospital capital available to the group of physicians to expand clinical services, staff, or operations. The infusion of resources can also provide administrative systems that might not be available to the medical practices separately, as well as comprehensive patient services to help manage care and assume financial risk. The availability of tax-exempt status also brings the foundation access to less expensive capital and exemption from sales and income taxes.

This approach is typically used by an IDS as a strategy to approximate direct physician employment without actually having to directly employ the physicians. It is particularly relevant in states such as California, where strict corporate practice of medicine laws restrict employment of physicians.

Establishing a foundation can be legally complicated, time consuming, and costly. As an organizational and governance strategy, these factors make it less attractive for smaller and financially weaker health care entities. There can also be requirements on the minimum number of physicians contracted through the foundation, as well as a requirement to conduct medical research and health education. The effective barrier posed by these requirements may preclude using a foundation model in rural and other areas.

Clinical Co-Management Models

Another model that may be more widely applicable is the clinical co-management model, which strives to align physician-hospital interests. This approach allows physicians to align with a hospital yet retain their independent practices. In the past, "co-management" companies have tended to focus on specific service lines, such as cardiovascular "centers of excellence" or orthopedic "joint centers." Within this model, participating providers buy shares in a separate management company, usually a Limited Liability Corporation (LLC), incorporated in the state where the physicians and hospital are licensed.

The co-management organizational structure enables physicians to hold leadership positions that are designed to influence and improve day-today clinical management and operations. Equity interests can be equal among the parties, or one party can have a controlling interest. Independent of how ownership is allocated, special rules and procedures can be established to protect certain rights, such as the number of board seats allocated to a hospital that supplies the initial capital.

A co-management company under this LLC structure may frequently contract with the hospital through a management services agreement to provide oversight and specific services. The company has the authority to negotiate and disburse financial incentives to the physician investors and hospitals. Often, a third party consultant facilitates the co-management model to ensure timeliness and success. This includes facilitating the structure, governance, incentives, and management services.

Under the traditional model, the hospital typically retains all legal, regulatory, and fiduciary responsibilities and requirements that it has under its license to operate. When adapting this model to an ACO, these responsibilities could be held by either the hospital or the physicians. The LLC provides a flexible framework that can be tailored to meet the clinical, operational, and other needs of the ACO participants.

Under this model, the LLC would be governed by a board of directors expected to include both hospital and physician representatives. Exhibit 2.3 provides an illustrative example of a co-management model.



EXHIBIT 2.3. POTENTIAL ACO CO-MANAGEMENT MODEL

Co-management structures tend to be very flexible, in part because it is relatively inexpensive to amend LLC agreements as conditions change. If necessary, LLC arrangements can be undone. The flexibility of the clinical co-management model helps make it an attractive approach where hospitals and physicians want to build a sustainable partnership and effective ACO. allow sufficient time to put in place the necessary infrastructure and processes, many of which are described in later sections of this toolkit. Aside from all of the internal administrative and clinical reorganization that an emerging ACO may require, there are also many important decisions and processes where leaders will need to work with external partners. Foremost are the agreements

THE BENEFITS OF LIMITED LIABILITY PARTNERSHIPS

The Limited Liability Corporations (LLCs) have several advantages as a structure for some ACOs. This structure carries potential tax benefits to the hospitals and physicians; limits personal risk and liability; and enables funds to be distributed to the investors (hospital and physicians). Moreover, the LLC structure is easy to legally set up and register, requiring little capital investment from individual investors.



POTENTIAL GOVERNANCE STRUCTURE DIAGRAM UNDER AN LLC

As a joint venture LLC, governance can be customized to meet the specific needs of each ACO. The figure above provides one illustrative example. A board of directors can be elected to oversee development of strategic, financial methodologies that include payment terms and risk sharing formulae, and to oversee distributions to its participating providers. The board of directors can also coordinate the implementation of the critical clinical operational changes required for the ACO. Meanwhile, specific tasks that are time-intensive can be assigned to appropriate standing sub-committees or to an ad hoc task force for recommendations. The recommendations can then be presented back to the LLC Board of Directors for approval and implementation.

2.4: MOVING FORWARD

FIRST STEPS IN SETTING UP AN ACO

A key consideration in setting up an appropriate ACO organization and governance is developing a clear and executable timeline. Organizations interested in forming an ACO should plan to that will need to occur with payers, which will include negotiations on the parameters of the shared-savings contracts, as well as determining how data will be shared.

As an immediate first step, aspiring ACOs should take stock of their internal capacities to successfully implement the ACO initiative. This includes identifying the key leaders of the initiative, as well as determining which services can be effectively and efficiently provided internally versus being outsourced. As part of this process, the leaders will need to identify partnering payers and test the willingness of potential provider groups to participate. The ACO providers will need to engage payers at an early stage for the ACO to succeed.

Suggesting specific timeframes for ACO implementation is difficult, as there is still no single roadmap to becoming an ACO, and much needs to be learned about their development and successful implementation. Nevertheless, one way for an ACO to set up its operations relatively quickly – particularly if it is not already a quite sophisticated, well-developed system – is to rely initially on contractual or leased services from entities with a proven track record of assisting providers achieve efficiency gains. Services can range from those provided by management service organizations (MSOs) or other similar organizations that serve physician-hospital entities to more narrowly focused data reporting and analysis vendors.⁵

For example, Marshfield Clinic is a large multispecialty group practice that is participating in the PGP demonstration. It is supported by an MSO and hospital partner. The MSO provides quality improvement, medical management, public reporting, contracting, and information management services to the multiple practices it has participating in the demonstration.⁶ Part 4 touches upon data reporting and analysis services and the potential for outsourcing such services.

Phased Implementation

ACOs will vary in their degree of integration, scope of services provided by ACO members, sophistication of care coordination and data analytics, and ability to bear risk. Consequently, successful organizational and governance models will both differ and likely evolve over time. An advanced ACO capable of successfully assuming two-sided risk with partial capitation, for example, requires a far more sophisticated and proven infrastructure than an ACO operating under a simple, one-sided shared-savings model based on fee-for-service payments. In general, new ACOs should take a phased approach to assuming more risk and more demanding ACO levels, progressing based on their level of experience and demonstrated capacity. This is particularly the case if providers have not been members of a long established and highly functioning, systems of care.

An organization need not reach the stage of full integration – an IDS – to be a successful ACO. In many cases, the optimal level of integration may be other than that displayed in current IDSs. To determine what level of integration is most appropriate for an organization, participants will need to examine their tolerance for financial and insurance risk as well as other infrastructure and patient population considerations that are explored more fully later in this toolkit.

CONCLUSION

The emergence of ACOs will largely depend on a mix of leadership and financial, cultural, and other considerations. The financial benefits must be significant enough to allow for the development of the required organizational entity; a successful ACO requires implementation of necessary patient care and administrative re-engineering. The specific characteristics and preferences of providers and patients in a particular local market will increase the challenges associated with implementing a successful ACO, a process which starts with identifying key leaders, selecting an appropriate ACO model, and developing required organizational and governance features. Like any business, the distribution of financial benefits must be skillfully handled and properly aligned with responsibilities to avoid becoming highly contentious. ACOs are a classic case of "the devil is in the details." As with many complicated undertakings that involve both process and cultural change,

ACOs may learn about essential details as they gain a year or two of actual experience. For that reason, newly formed entities may want to start as relatively simpler ACOs, designed with flexible operational, governance, and rewards structures that can rapidly evolve in response to data and analysis of changes in payments, practice patterns, and patient behavior.

ENDNOTES

1. At the time that this publication was being written, the Tuscon Medical Center was actively in the ACO planning phase and aiming to begin operating as an ACO in early 2011.

2. As discussed more fully in Part 3, the Dartmouth patient attribution algorithm assigns second priority to E&M codes provided by medical specialists, with third priority for E&M services from surgical specialists.

3. It is also expected that non-physicians such as nurse practitioners, would be eligible to be assigned patients in the ACO model.

4. Whether they are employees (or contracting with the ACO as independent practices), may influence how directly compensation of core ACO physicians is directly tied to shared savings realized by the ACO.

5. MSOs offer a range of support services to independent physician and ancillary service groups, such as purchasing or leasing equipment, contracting, billing, human resources, and regulatory compliance. MSOs typically include a hospital ownership interest and hence are often used with hospital and physician alignments.

6. Report to Congress. 2006. Physician Group Practice Demonstration: First Evaluation Report. <Available as of July 21, 2010 at https://www.cms.gov/reports/downloads/Leavitt1.pdf>.

Part 3

Accountability for Performance

David Axene, John Bertko, Dan Dunn, Bela Gorman, Steve Lieberman, Joachim Roski, Mark Zezza



ACCOUNTABLE CARE ORGANIZATION

PART 3: ACCOUNTABILITY FOR PERFORMANCE

The shared-savings concept is based on the notion of holding providers accountable for the cost and quality of care delivered to a defined population of patients. More specifically, providers' reimbursement will be linked to their ability to achieve greater value in care – lower costs and high quality. This requires that ACOs be able to produce meaningful evidence of their cost and quality effects. In this section, we discuss several key functions that an ACO will need to perform in order to provide such evidence, including:

- Patient Attribution;
- Budget Development;
- Payment Models and Incentives; and
- Performance Measurement.

An initial step for an ACO and its prospective payers is to agree upon a patient attribution methodology in order to determine the patients and providers that will be participating in the ACO. Once an ACO has identified participating providers and assigned patients, a budget can be developed to calculate the actual and the projected benchmark cost of care for the ACO. The establishment of this budget will allow an ACO to monitor costs in order to start identifying potential inefficiencies, as well as to understand the value of differing elements of attempted clinical transformation actions.

An ACO will also have to determine – with its prospective payers – the amount of risk it is willing to take in relation to the percentage of the shared savings it hopes to receive in order to determine an appropriate payment model. An ACO will also have to decide how to distribute its shared savings to the various providers to best incentivize the highestquality care at the lowest price. Finally, an ACO will have to establish and track performance measures that ensure an ACO's efforts to reduce costs occur through real improvements in the delivery of care.

Each organization will have to decide on how to approach these key design features in a way that best fits its organizational capacity and needs, as well as its position in the marketplace. The approaches and insights discussed below were gathered from the Centers for Medicare & Medicaid Services' (CMS) demonstrations, experience with the Brookings-Dartmouth ACO pilot sites, and the expertise of thought leaders and practitioners; however, these approaches do not represent the only feasible tactics for carrying out these critical functions. Rather, the suggested approaches below serve as a guide on how to start thinking about the development of elements required to become a functioning ACO.

Exhibit 3.1 is an overview of the relationship of these key functions with determining ACOs' cost impacts. The process discussed in Part 3 includes the full progression of identifying the patients for which ACOs will be held accountable, projecting spending benchmarks, measuring financial performance, distributing incentive payments, and quality measures with a direct link to provider reimbursements.

EXHIBIT 3.1. OVERVIEW OF ACO BUDGET PROCESS AND FINANCIAL PERFORMANCE

Patient Attribution

Patients are assigned to an ACO provider if they receive the plurality of non-inpatient care for evaluation and management services from that provider within a recent historical period. The ACO is responsible for all of the costs and quality of care delivered to patients attributed to providers who are exclusively members of that ACO.



ACO Budget Development

The historical spending amount is calculated and the projected benchmark spending amount is estimated. There are several important subtasks involved in this step.

Baseline Historical Data	Trend Estimates	Adjustments
This includes claims, exposure,	Actual spending is trended	Several adjustments are made
utilization, and cost per service	to the ACO contract period	to ensure actuarial reliability
statistics for a recent historical	based on historical trends,	and representativeness of the
period specific to the ACO	to determine the projected	data to finalize the projected
population.	spending amount.	spending amount. The
		benchmark spending amount is
		then determined based on the
		threshold



Performance Monitoring

Once the budget is finalized, the ACO should use a set of reports that will monitor the actual costs and compare them to the budget.



Payment Incentives

There are many different payment incentive arrangements. They range from "one-sided" shared savings within a fee-for-service environment to partial capitation arrangements with quality bonuses. The example described in this section is based on the one-sided shared savings model. ACOs would be eligible to receive financial performance incentive payments if the actual spending on their patients is below the benchmark, and they have met the quality targets.

3.1: ATTRIBUTING PATIENTS TO AN ACO

The first step towards developing the ACO financial framework is to determine the patient population that an ACO will assume accountability for care. Attributing patients to providers is an essential component of the ACO model for purposes of performance measurement (both cost and quality) and payment incentives. It is important to note that accountability for assigned patients lies with the ACO, not the individual provider. Therefore, patient attribution to providers is the way patients are assigned to an ACO.

There are several ways to associate patients with providers. One method, which is typically employed by health maintenance organizations (HMOs) or point of service (POS) plans, is for the payer or enrollee to select a primary care physician from the HMO or POS panel as the main source of care. This assigns all patients within a plan to a provider, even new enrollees without utilization history. However, this method is typically associated with plans that have a "closed" provider network.

An alternative approach is to use beneficiary attribution methods to identify the patients for which ACOs are accountable. This approach has the benefit of relying on patient preferences based upon where they have sought care in the past. Therefore, it is based on established patientprovider relationships. This approach does not require patients to select a provider. Furthermore, this approach supports "open" access to providers. This is particularly important to ensure that patients enrolled in preferred provider organization (PPO) or indemnity plans will not be restricted in their choice of providers or access to care. A potential downside of this approach is that individuals insured by a plan who have limited utilization may not be assigned. Also, patients may not know they have been attributed to a particular ACO. Some ACOs may find this problematic due to concerns that attribution approaches lessen their ability to oversee the care received by their attributed beneficiaries if

they are free to seek care from providers outside of their ACO network.

Patient attribution methods have been used by several shared-savings programs in the past. For instance, CMS use patient attribution methods in the Physician Group Practice (PGP) and Medicare Health Care Quality (MHCQ) demonstrations. Below, we discuss the patient attribution process in more detail.

Once the providers and the payers decide to form an ACO, a first step of the attribution model is for the ACO to determine who the eligible providers will be. More specifically, providers who are both members of and exclusive to the ACO will be used to assign patients to the ACO for accountability purposes.¹

The ACO gives this list of ACO providers to each participating payer. Payers may include Medicare, Medicaid, and multiple private payers. At this point, each payer runs the patient attribution algorithm on their covered patient population to determine which of their enrollees are assigned to the ACO. The assignment of the patients to the ACOs should be empirically developed based on where the individuals are receiving the plurality of evaluation and management (E&M) physician services.

The Dartmouth Patient Attribution Model

Various patient attribution methodologies exist. We will describe the Dartmouth patient attribution process in more detail below. The Dartmouth method emphasizes a longitudinal provider-patient relationship and limits the likelihood of patients who turn out to be high-cost from being excluded from the ACO (i.e., taking steps so that high-cost patients who had established a longitudinal relationship with the provider are not referred out or discontinued after implementation of the ACO).

Using the Dartmouth patient assignment methodology, patients are empirically assigned to a provider based on the patient's historical care

PGP PATIENT ATTRIBUTION MODEL

The PGP Demonstration uses a retrospective annual patient attribution model that assigns beneficiaries to a PGP based on where they receive their largest share of outpatient evaluation and management (E&M) services. Certain E&M services were excluded from the attribution methodology (e.g., emergency department visits), as not all services relate to a PGP's ability to manage and coordinate the health care of its beneficiaries.

One key distinction with the Dartmouth model is the retrospective feature. The retrospective approach taken helps ensure that providers treat all patients the same, as providers are unaware of which beneficiaries are participating in the Demonstration until the end of the performance period. Yet, while this approach prevents bias in patient treatment, it does not allow providers to easily target future care delivery interventions based on specific needs of their assigned patient population. To the extent the cost of care management capabilities increases with the number of patients, it also lessens economic benefits.

It was found that the PGPs in the Demonstration provided approximately 80 to 90 percent of the outpatient E&M services for their assigned beneficiaries and retained nearly two-thirds of these beneficiaries from year-to-year.² This finding alleviates some of the concern over not being able to properly oversee their patients care.

patterns, specifically the plurality of outpatient E&M visits. Each payer does this by using the most recent two years of claims data to assign patients to a provider based on their visits and the specialty priority of the provider. Each provider (both ACO and non-ACO providers) is classified into one of the three categories: primary care providers, medical specialists, and surgical specialists, based on their specialties. Exhibit 3.2 provides an overview of the patient attribution algorithm.

Primary care is given the highest priority, so even a single visit to a primary care provider trumps any number of visits to a medical specialist or surgical specialist. Thus, if a person had at least one visit to a primary care provider, he or she would be assigned to a primary care provider. If the patient visited more than one primary care provider, he or she would be assigned to the one whom the patient visited the most. If the number of visits among multiple primary care providers were equal, the patient would be assigned to the provider with the greatest number of days between the first and the last visit, to choose the one with the longest relationship. If the patient had only one visit with multiple primary care providers, the patient would be assigned to the provider with the most recent visit.

The same methods are used when a patient has had no primary care visits. If the patient had at least one visit to a medical specialist, he or she would be assigned to the medical specialist regardless of the number of visits he or she had with a surgical specialist. If the patient had no primary care or medical specialist visits, the patient would be assigned to the surgical specialist with whom he or she had the most visits. If a patient had no valid outpatient E&M visits within the two-year window, that patient would not be assigned.

Once each patient is assigned to a provider, the payers consult the list provided by the ACO to determine which providers are the ACO providers to whom patients can be assigned. Those patients assigned to a participating ACO provider are then assigned to that provider's ACO. Patients may be reassigned to the ACOs on an annual basis, with the exception of large groups of patients signing on to a private plan in mid-year.

EXHIBIT 3.2. OVERVIEW OF A PATIENT ATTRIBUTION PROCESS



For the Brookings-Dartmouth pilot sites, the participating payers and providers must agree to use this patient attribution methodology for ACO incentives. We recognize that different attribution models are in place for other delivery system reforms, such as the Patient-Centered Medical Home. While more testing is necessary, it appears reasonable for a provider system to use multiple attribution models for the various delivery system reforms they are participating in. For example, a provider system could use one attribution method for the medical home delivery system and a separate, distinct attribution method for the ACO delivery system. However, it is beneficial for all ACOs in an area to use the same attribution method to avoid having conflicts in patient assignment.

Exclusivity

It is important to note that the providers used for patient attribution should be exclusive to the ACO, while the providers not selected for patient attribution are free to participate in multiple ACOs. The exclusivity criterion allows for clearer evaluation of an ACOs performance and also alleviates concerns over gaming. For example, imagine if a Medicare provider is used for patient attribution in two ACOs. It may become difficult to keep track of which ACO is accountable for his or her patients. Furthermore, if the patients happen to be high cost, each ACO may be incentivized to try and disassociate itself from them.

Critical Mass

Another critical issue with patient attribution is the number of patients that are attributed to an ACO. An ACO should have a sufficiently high number of patients attributed for two reasons. The first involves the ability to obtain statistically or even practically meaningful results on the cost and quality impacts of ACOs. The statistical issue will be discussed in more detail with the benchmarking and performance measurement discussion later in this section. The second reason involves increasing the likelihood of achieving a critical mass of patients to incentivize providers to change care processes. Changes in core practice patterns and patient care management are expected under the ACO model. To support and reinforce the practice pattern changes, a sufficiently large percentage of the providers' patients should be enrolled in the ACO. Based on anecdotal discussions with industry experts, estimates of the desired critical mass can be expected to vary widely, ranging from 20 percent to 60 percent of the patients at an office or clinic location to be enrolled in the ACO.

Reaching critical mass may require the inclusion of both Medicare beneficiaries and commercial members. While Medicaid should be considered, the complexity, payment rates, and other unique attributes may add obstacles including to Medicaid in some states.³

It should also be noted that many ACOs will be contracting with multiple payers. Arrangements with commercial payers will vary based on the location and the market of the ACO partners. Potential contracts may be negotiated with a commercial carrier for fully insured business, selfinsured employer plans, or both. Although the characteristics of differing payers and membership may vary, the expected provider practice pattern changes and payment incentives should be aligned across all patients in the ACO.

It is also expected that ACOs will continue treating non-ACO patients. To the extent that non-participating payers benefit from the practice pattern changes adopted by ACO providers, their costs may drop without sharing the savings with the ACO providers, creating a "free rider" problem. There is thus an incentive for both ACOs and payers to achieve as much broad participation as possible.

Changes in Membership

After a patient has been attributed to a physician and the ACO, the assignment generally remains for a period of one year even if the patient changes his/ her care to providers outside of the ACO. Rules will be needed to make potential adjustments for patients who relocate, die, or lose coverage within the year. Although ACOs may consider alternative timeframes for handling enrollment issues, any approach adopted must limit the ability to "dump" high-cost patients while giving providers the opportunity to impact their patients' care. It is expected that ACO membership would remain relatively stable on an annual basis. Over time, membership would grow through the addition of new payers, ACO providers, or new groups of patients from existing payers.

3.2: DEVELOPING A BUDGET

Budget development within the context of the ACO framework entails analyzing historical utilization and cost data for the purposes of identifying areas for performance improvements, and developing benchmark spending targets that will determine shared-savings eligibility. Essentially, this process is used to measure the financial performance – the ability to control cost growth – of the ACO.

There are many different approaches to measuring the performance of an ACO. In the PGP and MHCQ shared-savings demonstrations, a quasiexperimental design has been used to determine shared savings. This approach compares spending and quality trends from the population served by intervention providers, ACOs, with similar trends in control populations, those not being treated by the ACO.

This cohort approach has several advantages. For instance, it more easily allows for the inclusion of trends, such as a sudden surge in utilization due to an unforeseen local disease outbreak, which would have been difficult to anticipate prior to the budget development process.

There are also several drawbacks with the control group approach. For example, there is often a lengthy lag between the end of the performance period and when the results can be analyzed due to the slow availability of claims information. As a result, providers often do not find out the results of their intervention until months – even years – after the performance period ends. Consequently, they would not receive shared-savings until much after they have made initial investments. The PGP Demonstration, for example, was already at the end of performance year five before results were available for the first three years.

Another challenge with using the cohort approach is ensuring that the control and intervention groups share similar risk characteristics. For example, in the PGP demonstration, diagnoses and other health information indicated that claims data are used to control for relative risk differences between the intervention and control cohorts. However, there are incentives for intervention providers to improve diagnostic coding practices from how they coded prior to participating in the demonstration. Financially, there is incentive to more fully document diagnoses as higher-risk scores ultimately translate into higher payments. Participating providers may also improve documentation to better target quality improvement initiatives. This issue can make it difficult to distinguish cost and quality impacts based on improved performance in care delivery from coding changes.

Another major drawback of the cohort approach is that it will become less viable over time. More specifically, as interest in ACOs grows – as well as many other value-based payment initiatives – especially with the start of the Medicare Shared Savings program in 2012, it will be increasingly difficult to identify control populations without significant intervention activity. Therefore, a budget projection approach using historical data appears to be a more sustainable approach.

The budget projection model builds on historical spending and utilization data from the ACO specific population to project budget benchmarks for future performance periods. The ACOs' actual spending in the performance period is compared to the spending benchmark to determine whether savings were achieved. Aside from addressing the increasing difficulty in finding adequate external control populations, there are a number of other benefits to the budget projection approach. Having prospective budget benchmarks gives providers the ability to judge their ongoing performance and set course corrections throughout the performance period, rather than having to wait until after the period to learn about its performance relative to a control cohort about which they had no comparative information. As discussed later on in more detail, the budget projection approach may also mitigate difficulties involved in controlling for relative risk characteristics, since the intervention population itself is used to develop the spending benchmarks.

While the budget projection approach has advantages, there are also several technical and theoretical problems. For example, budget projection models build historical trends into the projected benchmarks. This could unintentionally favor and reward ACOs with historically high spending growth from years of inefficient health care practices, as this trend extrapolates into higher benchmark spending targets that provide easier opportunities to achieve cost reductions. Setting benchmarks on a prospective basis under the budget projection framework also makes it more difficult to take into account unanticipated shifts in spending patterns from historical trends. Using a control group approach with retrospective spending benchmarks would better account for system-wide changes in health care delivery.

Besides the fact that the cohort approach will become less viable over time, another major factor for the budget projection model to become the predominate method for measuring financial performance in an ACO construct is that the Patient Protection and Affordable Care Act (ACA) has legislated such an approach for the Medicare shared-savings program. Furthermore, the cohort approach is not as feasible in the private sector due to limitations in the amount of data that would be available on non-ACO patients. Therefore, we focus on the budget projection in Part 3, which is also the method of choice for the providers participating in the Brookings-Dartmouth ACO pilot program. The following provides a discussion of the key issues involved in developing a budget projection model in the ACO framework, while also providing an illustrative example.

In order to develop these spending benchmarks, it is necessary to determine the baseline spending amount and appropriately project spending for the contract period, assuming there are no behavioral changes in practice patterns (i.e., projecting what spending would have been without implementation of an ACO). Developing an accurate ACO budget requires the actual claims and exposure data, significant data analysis and interpretation, and an understanding of ACO operations. Additional factors that need to be taken into consideration include the projected time period, the type of data to be used, any data anomalies, changes in the population, and development of appropriate assumptions and adjustments to be used. Detailed below are the key steps involved in developing an ACO budget, organized into four broad sections: baseline data, trend estimates, adjustments, and performance monitoring.

Baseline Data

Ideally, the ACO budget will be developed using baseline data, including existing claims, utilization, and exposure data. Claims information is reported based on either a paid basis or an incurred and paid basis. For example, paid claims in calendar year (CY) 2008 represent all the claims that were paid during that year, regardless of when the services occurred. Incurred claims in CY 2008 represent the claims for services rendered in CY 2008, regardless of when the claims were paid. For budget development purposes, incurred claims are more appropriate. However, when using incurred claims, the significant lag time between when a claim is incurred and when it is actually reported by the provider to the insurance carrier or Medicare Administrative Contractor (MAC) must be considered.
Generally, insurance carriers report incurred claims for a 12-month period with a three-month lag (runout), which is then adjusted for an incurred but not yet reported (IBNR) factor. For example, CY 2008 incurred claims paid through March 2009 would represent 12 months of data with three months of run-out. These incurred claims would then be increased by an IBNR factor to account for additional incurred claims in CY 2008 that have not yet been reported to the insurance carrier. Usually, the insurance carrier's actuary will develop an IBNR factor to "complete" the claims. Using claims development models, actuaries review the claims payment patterns and the historical trends to determine the appropriate IBNR factor to apply to claims. The IBNR factor decreases as the number of months of run-out increases.

For budgeting purposes, incurred claims should be reported by broad service or expense categories. The categories may vary by payers since each payer has different reporting mechanisms. When determining these categories, special attention should be given to the plan designs chosen by the ACOs members. For example, if there were a specific copayment for CT-Scans, it would be helpful to track the CT-Scans as a separate category. This will help the ACO to account for the impact of plan designs (and future plan design changes) on their budget. Some payers may not include certain services in their ACO contracts; for example, Medicare fee-for-service (FFS) ACOs may not include the outpatient pharmacy service (since they are paid separately under Part D). Some services are more important for specific populations; for example, home health is an important service for the Medicare population, but this is not typically the case for commercial plans covering the non-elderly population. Suggested categories are shown below:

- Hospital Inpatient
- Hospital Outpatient
- Lab/X-Ray
- Advanced Imaging
- Physicians (Primary Care and Specialty Care may be broken out separately)

The above discussion focused on a more traditional approach of developing the spending amount based on the service categories. As new payment methods evolve, such as the patient-centered medical home model, partial capitation payments, and bundled episode payments, additional analyses and modifications are needed. For example, with partial capitation payments, the capitation amount should be captured, and we would expect a cost and utilization reduction in the corresponding service categories.

The ACO needs to capture the total claims costs for each category. This includes the claims the payers are responsible for financially, and the members' cost-share amount. The total costs are defined as the "allowed claims." Note that these claim costs should also include the out-of-network claims, which will also count against the benchmark when determining the ACO's eligibility for its financial performance payments.

In addition to the claims, developing the budget requires exposure data, which are typically reported in the form of member months. Exposure is defined as the number of members enrolled in the ACO each month. For example, if there were 50 members enrolled in January, 49 in February, and 47 in March, the total member months for January through March would be 146. The time period of the exposure data must match the time period of the claims information. For CY 2008 incurred claims, one would need CY 2008 member month information. Exposure data are extremely important when there are significant fluctuations in enrollment. One cannot develop an accurate budget without it. For ACOs, member months are determined from the attributed members. As stated in the patient attribution section, patients are assigned once

- Outpatient Pharmacy
- Mental Health/Substance Abuse
- Durable Medical Equipment (DME)
- Emergency Room
- Other⁴

a year. Thus, normally there will not be any new patients, unless there is a large group joining during the mid-year. However, there are deaths, so the number of members will typically only decrease.

It is best to use the most recent 12-24 months of historical experience to develop the baseline data. Incurred claims and member cost sharing should first be adjusted for IBNR, and then divided by the member months (exposure) to calculate the claims costs per member per month (PMPM) and costshare PMPM for the various service categories listed above. An illustrative example is shown in Exhibit 3.3.

After the baseline claims PMPM are developed, the next step is to review the baseline utilization data. Typically, the utilization data is reported in important to understand the utilization assumptions that are reflected in the budget. Outpatient pharmacy utilization is typically measured in prescriptions per member per year. All other services are reported as visits per member per year, visits per 1,000 members per year, or services per member per year. Also, as mentioned above, there is a lag time between when a service is incurred and when a service is reported. Utilization data should be adjusted for the IBNR just as the incurred claims are adjusted. It is important to ensure that the reporting metrics are consistent among reports and from year to year. Changes in utilization reporting will impair an ACO's ability to monitor and measure their progress over time.

With the utilization data and the allowed claims PMPM, one can impute the average cost per

			CY 2008		
	Incurred	Incurred Claims	Member Cost	Member Cost	Total Allowed
	Claims	PMPM	Sharing	Sharing PMPM	Claims PMPM
Hospital Inpatient	\$3,600,000	\$60.00	30,000.00	\$0.50	\$60.50
Hospital Outpatient	\$4,500,000	\$75.00	15,000.00	\$0.25	\$75.25
Lab/X-Ray	\$1,260,000	\$21.00	-	-	\$21.00
Imaging	\$360,000	\$6.00	-	-	\$6.00
					-
Physicians					-
Primary Care	\$1,500,000	\$25.00	180,000.00	\$3.00	\$28.00
Specialty Care	\$2,000,000	\$33.33	270,000.00	\$4.50	\$37.83
					-
Pharmacy	\$3,060,000	\$51.00	780,000.00	\$13.00	\$64.00
Mental Health/Substance	¢700.000	¢10.00	100 000 00	¢0.00	¢14.00
Abuse	\$720,000	\$12.00	120,000.00	\$2.00	\$14.00
Emergency Room	\$180,000	\$3.00	30,000.00	\$0.50	\$3.50
DME	\$90,000	\$1.50	-	-	\$1.50
Other	\$730,000	\$12.17	-	-	\$12.17
					-
Total	\$18,000,000	\$300.00	1,425,000	\$23.75	\$323.75

EXHIBIT 3.3. BASELINE ALLOWED CLAIMS PMPB

Member Months CY 08 60,000

various forms, such as services PMPM, or services per 1,000 members per year. There are several measures for hospital inpatient utilization: days per 1,000, average length of stay, and admits or discharges per 1,000. It is best to receive all the measures of hospital inpatient utilization, since it is service. When performing this calculation, it is best to translate all utilization information into a PMPM metric. For example, if the hospital inpatient days per 1,000 members are 300, the PMPM is calculated by dividing 300 by 12,000 to get a resulting PMPM of 0.025. In other words, for every 1,000 members, there are 300 hospital days in a year, or 2.5 percent of a day for every member each month. To calculate the average costs per day, one would take the allowed claims PMPM (i.e., \$60.50), and divide it by the utilization .025, resulting in \$2,420 per day. The cost and utilization report includes all the baseline data the ACO needs to begin developing the ACO budget. A hypothetical cost and utilization report is shown in Exhibit 3.4.

Several adjustments can be applied to the baseline allowed claims PMPM to project to the applicable projection period. Since the baseline information is being projected to a future time period, several questions must be addressed, such as:

- What are the historical cost trends, and do we expect the same cost trends in the future?
- Would our reimbursement of services change, and if so, how?

	Reported	Cost/Day or Cost/	Utilization	Allowed Claims
CY 2008	Utilization	Service	РМРМ	РМРМ
Hospital Inpatient	300 days per 1000 members per year	\$2,420.00	0.025	\$60.50
Hospital Outpatient	7250 services per 1000 members per year	\$124.55	0.604	\$75.25
Lab/X-Ray	3360 services per 1000 members per year	\$75.00	0.280	\$21.00
Imaging	290 services per 1000 members per year	\$248.28	0.024	\$6.00
Physicians				
Primary Care	3.6 visits per member per year	\$93.33	0.300	\$28.00
Specialty Care	2 visits per member per year	\$227.00	0.167	\$37.83
Pharmacy	10 scripts per member per year	\$76.20	0.833	\$64.00
Mental Health/Substance Abuse	2.25 visits per member per year	\$74.67	0.188	\$14.00
Emergency Room	150 visits per 1000 members per year	\$280.00	0.013	\$3.50
DME	90 services per 1000 members per year	\$200.00	0.008	\$1.50
Other	1100 services per 1000 members per year	\$132.73	0.092	\$12.17
Total				\$323.75

EXHIBIT 3.4. COST & UTILIZATION REPORT

Trend Estimates

The budget projection model could be implemented in a number of ways, ranging from complex regression-based forecasts to simpler movingaverage trend extrapolations. It is also possible to use a negotiated approach that takes into account budget projections but also leaves room for ACO input. Below, we describe key considerations for projection calculations.

- What are the historical utilization trends, and are these trends expected to continue?
- How has the mix of services changed, and how would it change in the future?

Answers to the above questions will facilitate the development of the adjustment assumptions to be applied to the baseline claims PMPM.

	CY 2008			CY 2007			CY 2006		
			Allowed			Allowed			Allowed
	Cost/Day	Utilization	Claims	Cost/Day	Utilization	Claims	Cost/	Utilization	Claims
Service Category	or Service	PMPM	РМРМ	or Service	PMPM	PMPM	Day or	PMPM	PMPM
							Service		
Hospital Inpatient	\$2,420.00	0.025	\$60.50	\$2,251.16	0.025	\$56.28	\$2,084.41	0.025	\$51.59
Hospital Outpatient	\$124.55	0.604	\$75.25	\$114.27	0.570	\$65.13	\$105.80	0.545	\$57.71
Lab/X-Ray	\$75.00	0.280	\$21.00	\$71.43	0.257	\$18.35	\$68.68	0.240	\$16.49
Imaging	\$248.28	0.024	\$6.00	\$232.03	0.022	\$5.19	\$218.90	0.021	\$4.58
Physicians									
Primary Care	\$93.33	0.300	28.00	\$90.61	0.291	\$26.39	\$87.98	0.286	\$25.12
Specialty Care	\$227.00	0.167	37.83	\$216.19	0.159	\$34.32	\$207.88	0.154	\$32.04
Pharmacy	\$76.80	0.833	\$64.00	\$73.14	0.801	\$58.61	\$69.00	0.763	\$52.66
Mental Health/	\$74.67	0.188	\$14.00	\$72.49	0.175	\$12.70	\$70.72	0.165	\$11.69
Substance Abuse									
Emergency Room	\$280.00	0.013	\$3.50	\$260.47	0.012	\$3.10	\$242.29	0.011	\$2.77
DME	\$200.00	0.008	\$1.50	\$190.48	0.007	\$1.37	\$179.69	0.007	\$1.25
Other	\$132.73	0.092	\$12.17	\$126.41	0.089	\$11.25	\$119.25	0.086	\$10.30
Total			\$323.75			\$292.69			\$266.20

EXHIBIT 3.5. THREE-YEAR COST & UTILIZATION REPORT

The "raw" or unadjusted trend factor is one of the more difficult assumptions to determine, and there are many approaches to its development, from a simplified approach to ones that are more complex. All approaches should begin with a historical cost and utilization trend analysis, typically on the patient population expected to be treated by the ACO. The ACO should obtain the historical cost per service, utilization, and allowed claims data for each service category for a series of time periods. In addition, the ACO would need exposure or member month data for the various time periods. Ideally, the more time periods or data points one has, the more information there is to perform a thorough trend analysis. For example, retrieving data for the most recent 36 months and then grouping the data into 12-month, six-month, and three-month time periods can provide many data points, and through regression modeling, can result in a robust trend analysis. However, it may be difficult to retrieve this amount of data and the ACO may receive only a few data points, such as the annual data for the past three years. The data should be put in the form of a cost and utilization report as shown in Exhibit

3.5, which illustrates an annual three-year cost and utilization report.

Once the ACO has the historical cost and utilization report, it is easy to calculate the annual trends. This example involves the annual data for only the past three years and thus calculating annual trends is a simple division exercise. The above cost and utilization report can be used to derive the cost and utilization trend factors, as illustrated in Exhibit 3.6. As shown, for CY 2008, the hospital inpatient utilization trend factor is 1.00, or a zero percent trend. This means the utilization for this service did not increase from CY 2007 to CY 2008. The hospital inpatient cost per day trend factor is 1.075 or 7.5 percent, which means the cost per day increased 7.5 percent from CY 2007 to CY 2008. For all services, the overall claims PMPM increased 10.6 percent from CY 2007 to CY 2008.

If the ACO is able to retrieve more data points such as the six-month and the three-month time periods, annual trend calculation becomes a little more complex, and the resulting trends may need to be annualized. In order to determine how to annualize a trend, one must calculate the number of months between the midpoints of each of the time periods being compared. For example, if the two time periods being compared are July 2006 – December 2006 and January 2006 – June 2006, the midpoint of the first time period is Oct 1, 2006, and the mid-point of the second time period is March 1, 2006. The number of months between these two midpoints is six months and thus the resulting calculated trend is a six-month trend. To annualize this six-month trend, one would determine the monthly trend and then translate it to an annual historical pattern and to determine whether there is a trend toward the use of more expensive or less expensive services. It is important to consider all the factors that could affect the historical pattern and the projected mix of services. For example, it could be driven by a change in the physician practice patterns due to the newly implemented medical management or disease management programs. It could also be driven by a change in the member utilization due to the change in their benefit coverage. The result of this analysis should be reflected in the trend assumptions or in the adjustment factors.

	CY 2008			CY 2007		
	Cost/Day or	Utilization	Allowed Claims	Cost/Day or	Utilization	Allowed Claims
	Service	PMPM	РМРМ	Service	РМРМ	РМРМ
Hospital Inpatient	1.075	1.000	1.075	1.080	1.010	1.091
Hospital Outpatient	1.090	1.060	1.155	1.080	1.045	1.129
Lab/X-Ray	1.050	1.090	1.145	1.040	1.070	1.113
Imaging	1.070	1.080	1.156	1.060	1.070	1.134
Physicians						
Primary Care	1.030	1.030	1.061	1.030	1.020	1.051
Specialty Care	1.050	1.050	1.103	1.040	1.030	1.071
Pharmacy	1.050	1.040	1.092	1.060	1.050	1.113
Mental Health/	1.030	1.070	1.102	1.025	1.060	1.087
Substance Abuse						
Emergency Room	1.075	1.050	1.129	1.075	1.040	1.118
DME	1.050	1.040	1.092	1.060	1.040	1.102
Other	1.050	1.030	1.082	1.060	1.030	1.092
Total			1.106			1.100

EXHIBIT 3.6. ANNUAL TREND ANALYSIS

trend. If the six-month trend is five percent, the calculation to annualize this trend is (1.05^(12/6)), with a resulting annual trend of 10.25 percent. Once the cost and utilization trend information is calculated, the ACO must analyze the historical trend and understand the drivers, and then consider how the historical trends may change in the future. Separate analyses should be performed to consider possible changes in the costs and utilization patterns. For example, the ACO should perform a "mix-of-services analysis" to assess the

In addition, the ACO should review and reflect expected changes in reimbursements. For example, with the implementation of the patientcentered medical home model or the bundled episode payment model, the ACO would expect greater efficiencies while improving the quality of care. Further, analyzing the data at the episode or condition level could provide the ACO a clearer actionable path to reducing costs and increasing the quality of care delivered. Before the ACO determines the trend assumptions to be used in the budget development, it must perform all the relevant analyses. Below is a suggested list of analyses:

- Cost and Utilization Trend Report
- Mix of Services Analysis
- Provider Reimbursement Analysis
- Utilization Management Analysis
- Disease Management and other Medical Intervention Analysis

The ACO is now equipped to finalize the annual cost and utilization trend assumptions by service category. Before applying the trend assumptions to the baseline data, one must consider the time periods between the baseline data and the applicable ACO contract period. For example, if the baseline data represent CY 2008 and the contract is for CY 2010, the annual trend must be applied for two years. If the ACO has information that warrants different annual trends for CY 2009 and CY 2010, this should be reflected in the trend assumptions.

Exhibit 3.7 illustrates the application of the trend factors to the baseline data to calculate the unadjusted projected costs for the ACO contract period, using service categories. As shown, for the primary care physicians, the utilization PMPM for CY 2008 is 0.30, the cost per service is \$93.33, and the allowed claims PMPM is \$28 (0.30 x \$93.33). The cost and utilization trend assumptions for CY 2009 are three percent and four percent respectively, and for CY 2010, three percent and 4.5 percent. The CY 2010 allowed claims PMPM is \$32.28. The utilization trend factors are applied to the utilization PMPMs and the cost trend factors are applied to the cost/day or service. The allowed claims PMPM is calculated by multiplying the utilization PMPM and the cost/day or service. In this example, the projected CY 2010 allowed claims PMPM is \$391.83, which is 21 percent higher than the baseline allowed claims PMPM of \$323.75. The average annual trend is 10 percent (1.21^0.5).

In the above discussion, we have described an illustrative budget development process. Providers

and payers may consider alternative trend projection/budget development methodologies for the purpose of setting benchmark spending levels. This is particularly important if reliable baseline data is not available or if there are reasons to believe that the future trends would significantly diverge from the historical trends. In the text box below, we discuss the application of national or regional trends in the context of Medicare FFS ACOs. Providers and payers may also want to agree on other trend factors such as the use of the rate of growth in general inflation.

Adjustments

The projected spending estimates should be representative of the patient population that is treated by the ACO providers. It is possible that there may be anomalies in the baseline data that need to be adjusted accordingly, in order to ensure that the baseline estimates remain representative, when trended forward. Also, it is possible that there may be a significant population change in the ACO membership that could cause deviations from historical experience. In this section, we specifically address the risk adjustment factors and the highcost claimant adjustments.

Risk Adjustment

A population shift can occur between the time period of the baseline data and when one begins to develop a budget (e.g., from the recession recession). This shift can dramatically change the risk profile of the ACO's population and must be reflected in the budget. There are many ways to assess the risk profile of a population, such as using risk-adjustment models or actuarial age/sex factors. Using actuarial age/sex factors as an example, one should first review recent demographic data and then compare them to the demographics of members that represent the baseline data. For example, if the baseline data reflect CY 2008 and budget development begins in March or April of 2009, the ACO should request demographic data as of July 2008 and as of March or April of 2009.

	Allowed	Claims	PMPM	\$67.98		\$98.57		\$27.01	\$7.94		\$32.28	\$44.26	\$76.32	\$17.00			\$4.46		\$1.79	\$14.23	\$391.83
	Utilization	MMM		0.025		0.666		0.327	0.028		0.326	0.180	0.901	0.215			0.014		0.008	0.097	
	Cost/	Day or	Service	\$2,719.11		\$147.98		\$82.69	\$286.91		\$99.02	\$245.52	\$84.67	\$79.21			\$323.58		\$220.50	\$146.33	
	Utilization	Trend	Factor	1.000		1.050		1.080	1.070		1.045	1.040	1.040	1.070			1.050		1.040	1.030	
CY 2010	Cost	Trend	Factor	1.060		1.090		1.050	1.080		1.030	1.040	1.050	1.030			1.075		1.050	1.050	
	Allowed	Claims	PMPM	\$64.13		\$86.12		\$23.81	\$6.87		\$29.99	\$40.92	\$69.89	\$15.43			\$3.95		\$1.64	\$13.16	\$355.92
	Utilization	PM/PM		0.025		0.634		0.302	0.026		0.312	0.173	0.867	0.201			0.013		0.008	0.094	
	Cost/	Day or	Service	\$2,565.20		\$135.76		\$78.75	\$265.66		\$96.13	\$236.06	\$80.64	\$76.91			\$301.00		\$210.00	\$139.36	
	Utilization	Trend	Factor	1.000		1.050		1.080	1.070		1.040	1.040	1.040	1.070			1.050		1.040	1.030	
CY 2009	Cost	Trend	Factor	1.060		1.090		1.050	1.070		1.030	1.040	1.050	1.030			1.075		1.050	1.050	
	Allowed	Claims	PMPM	\$60.50		\$75.25		\$21.00	\$6.00		\$28.00	\$37.83	\$64.00	\$14.00			\$3.50		\$1.50	\$12.17	\$323.75
	Utilization	PMPM		0.025		0.604		0.280	0.024		0.300	0.167	0.833	0.188			0.013		0.008	0.092	
CY 2008	Cost/	Day or	Service	\$2,420.00		\$124.55		\$75.00	\$248.28		\$93.33	\$227.00	\$76.80	\$74.67			\$280.00		\$200.00	\$132.73	
		Service	Category	Hospital	Inpatient	Hospital	Outpatient	Lab/X-Ray	Imaging	Physicians	Primary Care	Specialty Care	Pharmacy	Mental Health/	Substance	Abuse	Emergency	Room	DME	Other	Total

EXHIBIT 3.7. UNADJUSTED PROJECTED SPENDING

PART 3: ACCOUNTABILITY FOR PERFORMANCE | ACO TOOLKIT

USING A NATIONAL TREND FACTOR

In the example described in the text, baseline data from the ACO specific population is used to derive a trend factor. This data reflects the practice patterns of the local market. It is well documented that among the FFS Medicare population, there are significant variations in practice patterns and thus, cost disparities across geographic areas. Given these geographic variations, a national or regional trend factor may be more appropriate for developing the spending benchmarks when working with a Medicare FFS population. In fact, ACA suggests that projected national spending growth be used as the basis for setting benchmarks in the Medicare Shared Savings program.

There are reasons to consider a national trend in both historically low- and high-spending growth areas. In the low-growth areas where providers have already demonstrated success in limiting cost growth, it may not be realistic to expect ACO providers to continue the same level of cost-control in the future. In contrast, areas with historically high-spending growth may have spending patterns reflective of poor quality and inefficient care. There may also be a perverse incentive for providers to drive up costs before starting an ACO. In these cases, ACOs would not want to incorporate that inefficiency into the trend factors, as inflated factors would make it easier for providers to earn rewards for care that is not necessarily reflective of better quality.

A national trend factor, which averages the high- and low-growth areas, has the advantage of mitigating the influence of geographic variation. This approach reduces the likelihood of rewarding historically high levels of spending growth that are indicative of low quality and inefficient care. It can also provide areas that have demonstrated success in controlling costs more achievable financial performance goals.

While a national trend factor may be sensible for a Medicare FFS population, in the non-Medicare market, there are additional variations in areas such as reimbursement design, benefit design, management protocols, and member risk composition. These additional variations make it less likely that a national trend factor is applicable or achievable for a local non-Medicare market.

Typically, demographic data are reported in five-year age intervals by sex for adults and varying intervals for children. Once the information is received, the ACO should calculate a weighted average age/sex adjustment factor for each of the time periods, using a standard set of actuarial age/sex factors. The ratio of the two age/sex adjustment factors from the two periods represents the change in the risk profile of the population between the two points in time. This example further assumes the risk profile will remain stable throughout the projection period, as the March/April period.

Exhibit 3.8 and Exhibit 3.9 illustrate the calculation of the age/sex factors using hypothetical demographics and age/sex factors. The standard age/sex factors in the illustration represent a typical commercial population (these factors and age groupings would be different for a Medicare population). The first table calculates the average age/sex factor of a hypothetical population as of June 2008. As shown, the weighted average factor is 1.05. The second table calculates the average age/sex factor for the population as of April 2009. As shown, the population grew from 4,413 members to 5,115 members, and the average age factor changed from 1.05 to 1.10. This suggests that the risk profile of the population has changed. The population became older and the average age factor moved from 1.05 to 1.10, suggesting that costs will increase by approximately 4.8 percent (1.10/1.05-1) from the baseline. With this data, the

	Male			Female			Total	
Age Cohort	Actuarial	June 08	Weighted	Actuarial	June 08	Weighted	June 08	Weighted
	Age	Enrollment	Factor	Age Factor	Enrollment	Factor	Enrollment	Factor
	Factor							
0-18	0.532	275	146.39	0.532	250	133.08	525	279.48
19-24	0.373	275	102.58	0.846	225	190.43	500	293.00
25-29	0.425	275	116.78	0.997	250	249.25	525	366.03
30-34	0.523	228	119.32	1.102	275	302.96	503	422.28
35-39	0.650	210	136.57	1.072	300	321.60	510	458.17
40-44	0.806	250	201.58	1.119	250	279.75	500	481.33
45-49	1.034	175	181.01	1.281	275	352.28	450	533.28
50-54	1.401	150	210.20	1.512	175	264.66	325	474.86
55-59	1.896	75	142.23	1.812	150	271.85	225	414.08
60-64	2.546	125	318.25	2.170	100	216.97	225	535.22
65+	3.321	75	249.08	2.646	50	132.28	125	381.36
Total		2,113	1,924	1.18	2,300	2,715	4,413	4,639
Weighted			0.91			1.18		1.05

EXHIBIT 3.8. JUNE 2008 AGE/SEX FACTOR CALCULATION

Factor

EXHIBIT 3.9. APRIL 2009 AGE/SEX FACTOR CALCULATION

	Male			Female			Total	
Age Cohort	Actuarial	Apr 09	Weighted	Actuarial	Apr 09	Weighted	Apr 09	Weighted
	Age Factor	Enrollment	Factor	Age	Enrollment	Factor	Enrollment	Factor
				Factor				
0-18	0.532	275	146.39	0.532	250	133.08	525	279.48
19-24	0.373	250	93.25	0.846	225	190.43	475	283.68
25-29	0.425	290	123.15	0.997	250	249.25	540	372.40
30-34	0.523	300	157.00	1.102	275	302.96	575	459.96
35-39	0.650	225	146.33	1.072	300	321.60	525	467.93
40-44	0.806	375	302.38	1.119	275	307.73	650	610.10
45-49	1.034	250	258.58	1.281	300	384.30	550	642.88
50-54	1.401	300	420.40	1.512	200	302.47	500	722.87
55-59	1.896	150	284.45	1.812	175	317.16	325	601.61
60-64	2.546	125	318.25	2.170	125	271.21	250	589.46
65+	3.321	100	332.10	2.646	100	264.57	200	596.67
Total		2,640	2,582	1.23	2,475	3,045	5,115	5,627
Weighted			0.98			1.23		1.10
Factor								

ACO should adjust its projected cost by 4.8 percent. The simplest approach is a bottom-line adjustment to the total claims PMPM. As shown in Exhibit 3.7, after trend, we have projected the CY 2010 total allowed claims to be \$391.83 PMPM. This unadjusted projected cost would then be increased by 4.8 percent to reflect the change in risk profile.

It should be noted that large shifts in the risk profile of the population are expected to be rare and typically would only occur if a payer adds a large employer group within the ACO's service area. Although it is critical to monitor the population make-up over time, it may not be necessary to make risk adjustments to the spending estimates if the population is fairly stable. ACOs are expected to have a large enough membership to ensure a stable risk profile over time.

Additional discussion on risk adjustment included more complicated models which control for specific diseases is included in the Part 3 Appendix.

High-Cost Claimant Adjustment

In the course of analyzing the baseline data and performing the trend analyses, the ACO may observe data anomalies. This may warrant further investigation and a review of the high-cost claimants for the baseline time period. Insurance carriers or third-party administrators should be able to provide a high-cost claimant report that shows every individual in the ACO population that has incurred a claim amount over a certain threshold, such as \$50,000. The report normally includes a member identifier, a claim amount, and primary diagnoses. The ACO can then ascertain if there were any shock claims or long-term illnesses during the base period.

In the case of a shock claim - for example, the birth of sextuplets - the ACO may want to adjust for this data anomaly, especially if the probability of a similar claim occurring is low. One approach to smooth out the shock claim is to remove all but, say the first \$50,000 of claims from the baseline claims PMPM. The percentage reduction in the baseline claims PMPM should then be applied to the resulting projected budget claims PMPM. As shown in Exhibit 3.10, \$400,000 was removed from the baseline allowed claims, which resulted in a 2.1 percent reduction in the claims PMPM. This 2.1 percent reduction should then be applied as an adjustment factor of 0.979 (1-2.1 percent), to arrive at the final CY 2008 allowed claims PMPM of \$323.75.

EXHIBIT 3.10. SHOCK CLAIM ADJUSTMENT

	CY 2008
Baseline Allowed Claims	\$19,425,000
Member Months	60,000
Allowed Claims PMPM	\$323.75
Shock Claim Claim Adjustment	\$450,000 (\$400,000)
Adjusted Baseline Claims	\$19,025,000
Adjusted Baseline PMPM	\$317.08
Percentage Adjustment	-2.1%

If the high-cost claimant report indicates some long-term illnesses, the ACO may want to add back in any claim amounts over \$50,000 to account for them. The exercise is similar to the shock claim adjustment shown in Exhibit 3.10, except that claims in excess of \$50,000 are being added in rather than taken out. The resulting adjustment would be an increase to the projected cost.

The ACO and the payer could also set up a full or partial reinsurance type of arrangement, where the expected costs associated with the highcost individuals in excess of a given threshold are converted into a PMPM and expressed as an adjustment factor to be applied to the projected cost. The level of the reinsurance threshold could vary with the size of the ACO membership (e.g., \$30,000 for 15,000 members and \$50,000 for 25,000 members). Smaller ACOs may warrant lower thresholds, as there is less ability to spread the risks associated with the high-cost cases. This arrangement would help to smooth out the costs associated with the high-cost but relatively infrequent cases, such as solid organ transplants and very expensive low-birth weight babies.

Summary of Adjustments

In this illustration, the baseline claims costs are adjusted by a trend adjustment, an age/sex adjustment, and a high-cost claimant adjustment. Exhibit 3.11 summarizes the adjustments to the baseline and the resulting CY 2010 spending projection.

EXHIBIT 3.11. CY 2010 SPENDING PROJECTION

CY 10 PMPM Spending Projection	
CY 08 Allowed Claims PMPM	\$323.75
Age/Sex Adjustment	1.048
High Cost Claimant Adjustment	0.979
CY 09 Trend Factor	1.0994
CY 09 Allowed Claims PMPM	\$365.18
CY 10 Trend Factor	1.1009
CY 10 Allowed Claims PMPM	\$402.01

Note: This example assumes the age/sex adjustment and the high cost claimant adjustment were 1.0 for the historical period. The adjusted projected spending (\$402.01 PMPM in our example) would be used to calculate the spending benchmark for an ACO beginning in CY 2010. Its calculation is discussed below, under the Payment Incentives section. The spending benchmark is used to measure the performance of the ACO spending growth. When the ACO achieves the quality goals and has lower spending levels relative to the benchmark, it will receive the incentive payments.

Sensitivity Analysis

It is important to perform sensitivity analyses on the assumptions used in setting the budget to gain an understanding of the potential range of variations. The results of the sensitivity analysis will eliminate many surprises when the actual claims costs are not within the calculated budget. Additionally, it will draw attention to which assumptions are more sensitive than others to the overall claims projections. Since the trend assumptions are the most important factor when determining the overall spending, the sensitivity analysis should be focused on this assumption. In the example used throughout, the ACO-specific trend was used in the budget projections, meaning that the data specific to the ACO were reviewed and used to determine a trend assumption. Another approach may be to review the national data and determine a national trend assumption. If the national trends are significantly different from the ACO trends, it is important to understand why. There could be specific reasons for the variation, and the ACO budget should account for this.

Performance Monitoring

Once the spending benchmark, or target, is finalized, the ACO should design a set of reports to monitor the actual costs and compare them to the benchmarks. At a minimum, the ACO should review these reports on a quarterly basis. Information from these reports can highlight problem areas and allow the ACO to intervene and manage the claim costs. These reports can also assist the ACO in developing the spending benchmark for future years. A "benchmark to actual" report compares the benchmark claims PMPMs to the actual claims PMPMs by service category. If there is a significant variance, one can drill down by the cost and utilization breakdown between the benchmark costs and actual costs. A member demographic report can indicate the risk profile of the population and how it is changing. Finally, a high-cost claimant report can identify any shock claims or long-term illnesses that were not planned for in the budget.

Sometimes, the variances between the benchmark and the actual claims are due to random fluctuations, particularly when one is looking at monthly data or comparisons by service categories. A rolling three-month average or a rolling six-month average would be more stable than monthly data.

Pro Forma Budget Development

It is expected that ACOs will use a variety of welldefined interventions to improve the quality of care provided to their enrollees while reducing the cost of care. As these interventions are likely to cost ACOs money and resources to implement, it is critical that ACOs develop a pro forma budget detailing their expected costs and savings. This step is also necessary for ACOs in projecting the total amount of incentive payments they could potentially achieve.

For example, suppose an ACO implements a patient navigator program for patients with chronic conditions that are recently discharged from a hospital. This program increases the ACO's administrative costs by \$50,000 and reduces the claim costs through reduced readmissions by \$100,000. The ACO would need to share in at least 50 percent of the claims savings (\$50,000) with the payer in order to break even on the investment for the new program in one year.

Due to the variation of each intervention, it is difficult to offer specific guidance in the development of a pro forma budget. In general, each of the services in the budget needs to be considered for a potential change due to the intervention. Both additional expenses, as well as potential cost savings, will need to be considered for the contract period.

As many of the interventions may be newly developed with limited or no historical evidence for effectiveness, pro forma budgets may essentially be best guesses or extrapolations from limited experiences. Therefore, these estimates should continually be updated as part of the regular budget monitoring process, using any new and actual financial information that becomes available. Monthly or quarterly updates will help assure that projections are as close to being accurate as possible.

Adjusting Benchmarks Over Time

Providers and payers are likely to consider multiyear ACO contracts. Multi-year agreements will help foster long-term, lasting improvement impacts. The PGP demonstration began as a five-year program, as did the MHCQ demonstration. ACA requires a three-year commitment for providers interested in joining the Medicare Shared Savings program beginning in 2012. Private sector initiatives such as the Blue Cross Clue Shield of Massachusetts Alternative Quality Contract (BCBS MA AQC) and the Brookings-Dartmouth ACO pilot program also require multi-year participation. Given that there is still only limited evidence on the budget impact of specific interventions, and given that reliable baseline data used to establish benchmarks is not always available, participating providers and payers should consider reviewin and if necessary updating - benchmarks at regular, predefined intervals. For example, the BCBS MA AQC program rebases its budget benchmarks annually.

There are a number of reasons why both payers and providers may want to consider rebasing benchmarks based on more recent data. For example, recent data could suggest that exogenous factors – such as an economic recession or development of new medical technology – could cause future spending to diverge significantly from past trends, which could make current benchmarks less reflective of expected spending under ceteris paribus assumptions. Additionally, payers may want to recognize increases in efficiency and consider making the spending target more difficult for ACOs to achieve in proceeding years.

How payers and providers choose to negotiate whether and how benchmarks should be updated will require important consideration. Payers and providers should anticipate ways to make rebasing adjustments in their initial contracts. For instance, if payers and plans could agree on a particular updated factor – such as zero percent, general inflation, or a national or regional growth rate – they could also agree to a partial adjustment to past trends based on national or regional trends, or some sort of rolling average approach.

3.3: PAYMENT MODELS AND INCENTIVES

In general, ACOs would be eligible to receive financial performance incentive payments if the actual spending on their patients is below the benchmark, provided that the quality performance standards are met or exceeded. In this section, we discuss some of the key issues that must be considered when developing such a payment system.

There are many different payment models available to an ACO. They range from a "one-sided" shared savings within an FFS environment, to a range of limited or substantial capitation arrangements with quality bonuses, as shown in Exhibit 3.12.



EXHIBIT 3.12. CONTINUUM OF PAYMENT METHODOLOGIES

Ideally, an ACO will transition over time to implement payment models with increasingly more risk, resulting in the ability to retain a higher percentage of shared savings for being more accountable for cost and quality, as shown in Exhibit 3.12. As organizations grow more comfortable managing risk and become more clinically integrated through new care strategies and more sophisticated health IT, they can progress from a "one-sided" payment model (Level 1) to a "two-sided" payment model (Level 2) where an organization is liable to share in the costs if their spending exceeds their projected benchmarks.

Once an ACO becomes experienced and comfortable managing the added risk of a symmetric payment model, they could then advance to a partially capitated payment model, where some services remain on a FFS reimbursement basis, while others are reimbursed by a fixed amount per patient. For example, an ACO could received a pre-paid risk-adjusted capitated amount to cover all ambulatory care services for its ACO patients, and then have a bonus/withhold payment (i.e., a shared-savings model) based on the traditional discharge level reimbursement rates and spending targets for their inpatient services. Progressively moving towards a payment model that accepts more risk will help further incentivize an ACO to be more accountable for the cost and quality of their provided care.

Regardless of the payment model level an ACO is operating in, a necessary step to any financial performance model is to calculate the actual expenditures incurred during the financial performance period. In our illustrative example below, we define the financial performance period as a 12-month period. The period should be long enough to obtain a large enough sample of claims in order to estimate the representative spending amounts. Periods longer than a year run the risk of displacing the financial incentive from the time when services are being performed. The methodology for calculating the actual spending amount is similar to the above discussion on calculating the baseline incurred claims. It may be necessary to adjust the data for anomalies such as high-cost claimants. Also, it may be necessary to determine if there has been a shift in the risk profile of the population.

Once the actual spending amount has been calculated, and assuming quality benchmarks are met or exceeded, a comparison to the benchmark spending would determine if the ACO is eligible for the bonus payments. For incentive payment purposes, the comparison between the actual and the spending benchmark is performed on the aggregate claims level, not by the service category level.

Three key features to consider when formulating the bonus payments are (1) the use of a savings threshold, (2) the percentage of the savings to be shared, and (3) whether it should accept an asymmetric or symmetric risk model. These features can essentially be used as tools to balance the levels of risk that providers and payers are prepared to take in their ACO efforts.

Savings Threshold

In Exhibit 3.13 below, the savings threshold is two percent, meaning that financial performance bonuses are only distributed if the actual spending growth is lower than the projected spending growth by more than two percent. The target – or the benchmark spending growth – is therefore calculated as the projected spending growth less two percent.

Small fluctuations in actual spending amounts are to be expected. The use of the two percent savings threshold is meant to avoid making bonus payments for savings that essentially happen by chance. Thresholds can also be used in two-sided models to protect providers from financial risk against random losses. ACOs may want to consider setting the level of the threshold as a factor of the size of the ACO membership. For example, smaller ACOs are more susceptible to larger variation and therefore a higher threshold, such as four percent, may be more appropriate. In fact, ACA establishes a minimum Medicare beneficiary panel of 5,000 for ACO participation in the Shared Savings program beginning in 2012. The greater the population size, the less variation that would be expected and the more predictable spending becomes, so a smaller threshold would be required.

The level of the threshold should also vary with the level of risk that the providers are willing to take. For instance, under a Level 3 global budget approach, providers may participate in first-dollar savings, as well as first-dollar losses.

Percentage of the Savings to be Shared

In our illustrative example, 50 percent of the savings between the actual spending growth and benchmark spending growth is eligible to be shared with the ACOs. The other 50 percent is retained by the payer as savings. ACOs may want to select a different distribution level such as 80/20, with 80 percent going to the providers and 20 percent to the payer. Considerations that may factor into this decision are (1) the amount of expected savings that an ACO could feasibly accrue, and (2) the cost of the cost-savings interventions that the ACO would implement. Ideally, the bonus payments should at least offset the intervention costs. Additionally, the percentage should also vary with the payment model used. Models where the providers have greater financial risk should be associated with higher percentages for the providers to balance the risk-reward relationship.

PAYMENT MODELS IN MEDICARE SHARED SAVINGS PROGRAMS

ACA legislates that savings thresholds and percentages be used for the Medicare Shared Savings program beginning in 2012, the parameters of which have yet to be determined as of the writing of this document. Legislation also suggests the potential for using both one-sided and two-sided models.

In the PGP demonstration, the shared savings threshold is two percent. PGPs qualify to receive up to 80 percent of the total savings based on how they perform on quality benchmarks. The other 20 percent reflects savings to the Medicare program.

In addition to the opportunity to share in any measurable savings, PGPs are also somewhat accountable for potential losses. More specifically, if spending exceeds the spending benchmark by two percent in a performance period, the excess spending is carried forward as losses and are deducted from any bonuses earned in future years.

The shared savings thresholds differ for the two sites in the MHCQ demonstration that have a sharedsavings model based on total patients costs. For the Indiana Health Information Exchange, the savings threshold is set by a formula that is dependent upon the size of the intervention and comparison populations. Initial estimates place the threshold at around 1.5 percent. For the North Carolina Community Care Networks, Inc., the threshold is set at 2.9 percent for the first two performance years when a relatively small panel of dual-eligible beneficiaries is included in the demonstration. From year three to five, the total savings threshold is reduced to 1.5 percent, as the general Medicare FFS population is included in the demonstration.

Asymmetric or Symmetric Risk

In our example, we assume that the ACO can only share in the savings if its actual spending growth is below the benchmark spending growth and that the payer assumes full costs of the spending in excess of the benchmarks. This scenario is known as a one-sided risk or asymmetric payment model.

An alternative is a two-sided or symmetric risk situation, where the ACO shares in the costs if they exceed the benchmark spending amounts. A symmetric risk model may provide stronger incentives for the ACO providers to achieve more efficient care, but could also deter many providers from deciding to participate in an ACO payment model.

Example of A Shared Savings Model

Exhibit 3.13 provides an example of how these payments would work in a one-sided shared-

savings model. In this example, the projected allowed PMPM is \$402 in 2010, followed by \$434 and \$469 in 2011 and 2012, respectively. After taking into account the two percent saving threshold, the PMPM targets (or benchmark) for the shared-savings are calculated to be \$394, \$426, and \$460 for 2010, 2011, and 2012, respectively.

In 2010, the ACO attains an actual PMPM amount of \$394. In this case, there is no shared savings because the ACO did not reduce the costs by more than the two percent threshold.

In 2011 and 2012, the ACO is able to reduce the costs by three and five percent, respectively. Therefore, shared savings is achieved in both years. In this example, the ACO would receive the incentive payments of \$2.50 (50 percent of \$5) PMPM in 2011, and \$7.50 PMPM (50 percent of \$15) in 2012.



EXHIBIT 3.13. EXAMPLE OF A ONE-SIDED ACO PAYMENT MODEL

Note: Numbers may not add up due to rounding. The target represents the projected spending less the 2 percent savings threshold.

As mentioned above, the one-sided model is only one of the methods for implementing an ACO financial performance payment. An advantage of this model is that it demands the least disruption in the current administrative and delivery systems; however, a disadvantage is that the payments are still tied to a FFS system, which provides incentives for overutilization of health care services. It also does not provide additional flexibility for ACOs to alter the way services are reimbursed. For example, high-value services, such as preventative care that have low reimbursement rates, may still be underutilized.

There is no single ACO model that is the best for all the situations, as each has its advantages and disadvantages. As more ACOs begin implementation, it will be important to learn what works and doesn't work. Given the wide variation in local circumstances, such as organizational and governance structure, experience with previous risk, and historical spending trends, it can be expected that there will also be variation in the ACO payment models that are being utilized.

3.4: DISTRIBUTION OF SHARED SAVINGS

The distribution of the shared-savings bonuses will be an ACO-specific decision. ACOs will need to consider the incentives necessary to motivate the providers in making the required practice pattern changes.

In the discussion below, we lay out three potential "pools" for distribution. In general, the incentive pools could focus on rewarding either those providers making the key practice pattern changes or those affected by the changes. The methodology of the incentive pool allocation should be established up front as part of the process of organizing the ACO. The pools described below are just examples of how this allocation could be accomplished. The portion of the aggregate incentive funds directed to the pools will vary by the individual ACO and by year of operation. For example, ACOs that are established by fully integrated delivery systems may already have internal financial incentives established with participating physicians and other providers. In this case, any shared savings bonuses could presumably be used by the ACO to invest in further care improvements or for other purposes.

Shared Savings to Offset Revenue Reduction

Some of the ACO partners may see a significant reduction in revenue due to the change in practice patterns. An ACO may choose to use a portion of its shared savings to partially compensate providers who are affected by these changes, such as hospitals or some specialists.

It should be noted that while the per patient per year revenue amount may decline for some providers such as hospitals and specialists, not all hospitals and specialists will experience an overall revenue reduction, as the reduction could be offset by ACO's market share expansion and patient volume increase. In evaluating the effects on particular providers resulting from practice pattern changes, it is also important to focus on both "top line" revenue and "bottom line" net earnings. If revenues are reduced, but costs are reduced by a greater factor, profitability can be increased. Shared savings allocations should take into account cost savings that help offset the revenue reductions.

Shared Savings for Cost Savings

The objective of this pool is to recognize the core physicians – those used for patient assignment – who generate savings by improving management of the patient's health resources and the other physicians who utilize episodic resources effectively. Allocation of funds should consider the relative contributions of each of the bonus eligible ACO providers.

Incentive Pool for Return of Capital

Essentially, this pool is to distribute the remaining net income back to the principle ACO investors or partners based on their capital contributions to the ACO.

ACO Group Operating Cost

The ACO is likely to incur organizational costs and expenses from developing innovative methods for coordinating care of the ACO patients. As part of the feasibility analysis before starting operations (e.g., a pro forma), these costs need to be estimated, and ACOs need to have a plan for funding them. These costs may need to be covered before distributing shared savings. If there are no savings or if the savings are not sufficient to pay for the ACO costs, contributions by the ACO partners will be required to cover the costs.

"Spillover Effects" To Non-ACO Patients

Physicians and other providers tend to treat all patients in a similar manner of practice. To the extent that ACOs succeed in generating savings, total revenues paid for health services will decline and ACO incentive bonus payments may be used to mitigate this reduced revenue.

To the extent that non-participating payers benefit from the practice pattern changes adopted by ACO providers, their costs may drop without sharing the savings with the ACO providers, creating a "free rider" problem. Therefore, it is imperative for an ACO to try and involve multiple payers, constituting the majority of the ACO's served patients.

3.5: PERFORMANCE MEASUREMENT

Another critical ACO design feature is the implementation of a quality measurement strategy to ensure the financial benefits of achieving cost targets are contingent on meeting health care quality performance targets. Performance results provide ongoing information and feedback to providers to help improve patient care, to incorporate patient's feedback and insights into care delivery strategies, and to assure the public that any cost savings coincide with improvements in care.

In this next section, we discuss several major challenges to implementing a comprehensive performance measurement system. Initially, many organizations will only be able to track a basic set of measures, but their ability to track patient-centric results is assumed to improve significantly over time. Summarized below in Exhibit 3.14 are some of the key components and considerations involved with measuring health care quality in the ACO framework.

EXHIBIT 3.14. KEY CONSIDERATIONS FOR MEASURING HEALTH CARE QUALITY

Selecting Measures	Measures should track the results along the continuum of care, covering a wide range of services and a broad range of quality of care goals, including care coordination, population health, overuse, and patient engagements. Measures should be well established and preferably nationally endorsed.
Data Sources and Collection	Quality measurement relies on multiple data sources. Sources include administrative claims data (e.g., medical and pharmacy), laboratory and clinical records, electronic medical/health records, registries and patient-generated information, such as patient surveys.
Standard Set of Measures	We propose a starter set of standard ACO measures that are based on administrative claims data. We discuss a pathway to expand performance measurement to be based on clinical and other data sources over time.
Targets	Under the accountability-payment framework, financial incentives are contingent on providers meeting or exceeding performance targets. We describe a general framework of tying performance to financial rewards for the ACO pilot sites.
Performance Calculation	We discuss various methods of calculating performance results, including the use of risk adjustment and composite scores.
Validation of Measures	Accuracy and consistency are both important. For accuracy, verification processes should ensure all calculations are done in accordance with technical specifications. To evaluate the effectiveness across ACOs, the validation process should verify data collection and aggregation methods are implemented consistently.
Public Reporting	A core principle of ACOs is to be accountable for the quality of care provided. As such, public reporting of the quality performance is a key aspect of implementing an ACO quality improvement program.
Consistency with Other Reforms	There is a wide range of payment reform initiatives, including expanded use of pay-for- performance programs, medical homes, and ACOs. Each of these requires the use of performance measures. Having consistent or standardized measurements across these initiatives would greatly assist in the evaluation and implementation of these programs.

Staging the Implementation of Performance Measures

We envision phasing in the implementation of performance measurement to align with the ability of accessing multiple data sources. In Exhibit 3.15, we describe three phases of implementation. We expect that over time, those at the beginning phase will reach the advanced phase, where performance measures can effectively address multiple priorities spanning the continuum of care and are outcomeoriented. The various phases are described below.

- Basic Phase. ACOs with a "basic" health IT infrastructure predominantly rely on administrative data, with limited access by providers in their ACOs. Health care quality performance measures for these organizations will be limited to those that can be computed reliably using claims data.
- Intermediate Phase. ACOs with an "intermediate" health IT infrastructure will utilize clinical data in addition to the claims data, particularly for primary care and chronic care management purposes. These ACOs may be able to routinely access and receive electronic laboratory results from their contracted laboratories. Some clinical data may also be available from specific registries (e.g., immunizations) maintained for their organizations or from nationally-maintained registries (e.g., interventional cardiology).

- Advanced Phase. ACOs with an "advanced" health IT infrastructure will have comprehensive access to clinical data collected through their widely deployed and interoperable ACO-wide EHRs. Moreover, these ACOs also will have the ability to directly collect patient-generated information about their care experience. These ACOs will be able to track and measure patients' outcomes and experience across multiple care settings, such as inpatient care, tertiary/long-term care, specialty outpatient care, and primary care.
- It is expected that over time, with additional incentives available through the Federal Government and others, ACOs will quickly expand their health IT infrastructure to measure care quality more comprehensively, and reap associated rewards of being able to demonstrate superior quality and outcomes along the care continuum.

EXHIBIT 3.15. EXAMPLES OF POTENTIAL PERFORMANCE MEASURES FOR ACOS WITH BASIC, INTERMEDIATE, OR ADVANCED HEALTH IT INFRASTRUCTURE

PRIORITY AREAS	Basic Phase: CLAIMS-BASED MEASURES ACOs have access to medical, pharmacy, and laboratory claims from payers	Intermediate Phase: LIMITED CLINICAL AND SURVEY MEASURES ACOs use specific clinical data (e.g., electronic laboratory results) and limited survey data	Advanced Phase: COMPREHENSIVE PATIENT-FOCUSED MEASURES ACOs use more complete clinical data (electronic records, registries, etc.) and robust patient-generated data (Health Dick Approices, functional status)
Care Effectiveness/ Population Health	 Cancer Care Screenings Diabetes care (LDL and H1c tests, eye exams, etc.) Coronary Artery Disease care (LDL test) 	 Immunization rates for children and adolescents Patients with diabetes whose blood sugar (H1c) are in control Patients with diabetes or ischemic vascular disease whose lipids (LDL) are in control Patients with hypertension whose blood pressure are in control 	 Comprehensive health risk summary score (BMI, blood pressure, cholesterol, smoking, exercise, alcohol) Stage-specific quality of life and functional outcomes for common cancers Quality of life and functional outcomes for common conditions (e.g., AMI, hip replacement, diabetes)
Safety	 High-risk medication for the elderly Appropriate testing for patients using high- risk medications 	"Never events" in hospitals	 Hospital infection and risk adjusted mortality rates Outpatient medication errors
Patient Engagement	•	 Physician instructions understood (CAHPS) Care received when needed (CAHPS) 	 Care plans – patient activation and engagement in chronic/ other conditions Preference sensitive conditions level of information communicated regarding patient choice (e.g., knee surgery) Patient preferences – adherence to design and execution of care plan (e.g., advanced directives)
Overuse/ Efficiency	 Imaging for low back pain (in absence of "red flags") during first 30 days Inappropriate antibiotic prescribing Utilization rates of select services (e.g., C-section) 	 Episode-based resource use – linked to quality measures for common medical (e.g., diabetes, AMI) and common surgical conditions (e.g., hip replacement) 	 Episode-based resource use – linked to quality of life, functional and patient engagement measures for common medical (e.g., diabetes, AMI) and surgical conditions (e.g., hip replacement)

Selecting Measures

While primary care is a critical element of the ACO model, ACOs are accountable for all care delivered to their patients, including specialty care and services provided in non-ambulatory settings – inpatient hospitals, home health, and skilled nursing homes – regardless of whether or not the services are delivered by ACO providers. Developing a broad set of measures covering the full spectrum of these services and addressing multiple priorities will provide incentives for providers to focus on population health as well as interventions to improve care.

Use Well Established and Validated Measures

Consensus around selected measures can aid with acceptance of measures by all stakeholders, including participating providers in the ACOs. Entities such as the National Quality Forum (NQF) have endorsed useful performance measures for selected priorities. The above characteristics are very helpful for providing momentum for the quality improvement and financial reforms implemented by the ACO.

To reduce overall measurement burden, selected measures should ideally be aligned with the use of measures for other purposes, policy objectives, and payment reform initiatives across the public and private sector.

Finally, selected measures should rely on nationally consistent specifications (e.g., as contained in NQF endorsed performance measures) as well as nationally consistent rules for data collection and aggregation (e.g., as being defined through efforts of the Quality Alliance Steering Committee).5

While the NQF has endorsed more than 500 measures, many gaps covering critical priorities for care improvement – such as care coordination, proximal and long-term outcomes for many critical conditions – remain. In addition, detailed data

THE NATIONAL QUALITY FORUM CONSENSUS PROCESS

Using its multi-stage 'consensus development process' – designed to call for input and take into considerations the interests of stakeholder groups from across the health care industry – NQF fosters consensus among a wide variety of stakeholders around specific standards that can be used to measure and publicly report health care quality. From this, the NQF has developed a portfolio of endorsed performance measures that can be used to measure and quantify health care processes, outcomes, patient perceptions, and organizational structure and/or systems that are associated with the ability to provide high-quality care.

These endorsement processes ensure that measures:

- Characterize important processes and outcomes of care;
- Produce scientifically sound and statistically reliable results;
- Are feasible to collect efficiently; and
- Are deemed useful by payers, consumers/ patients, and others for taking action.

collection and aggregation details are not available for many measures. With the recent passage of health care reform legislation it is expected that significant federal funds will be invested to develop and test needed performance metrics for high priority areas. It is expected that these newly developed metrics and their associated data collection processes will be integrated rapidly for tracking the ACO performance. Where relevant "endorsed" measures are not available, it may be possible to use measures that are in process for multistakeholder endorsement.

Data Collection

Performance measurement efforts are supported by a number of different data sources, including administrative data, electronic clinical data, and patient-generated data (e.g., through surveys). Some of the performance measures can be calculated using data from a single source, and other measures require data elements from multiple sources. There are three main types of data sources that should be accessible for ACO quality measurement.

1. Administrative data – enrollment, as well as medical and pharmacy claims. Enrollment and administrative claims data can be obtained from payers. Claims data covers large populations. Several performance measures can be reliably calculated using administrative claims data, whereas other performance measures often rely on clinical data that is not as readily available as claims data. Therefore, measures for the initial phase of ACO implementation are often based on administrative data.

2. Electronic clinical data. Certain performance measures require rich clinical data - from electronic medical or health records, laboratories, and standalone clinical data systems such as clinical registries - and cannot be computed using only administrative data. The availability and ability to access such clinical data is expected to significantly increase over the next few years. Many organizations are now able to access and "process" clinical data for measurement purposes (e.g., receipt and integration of laboratory results provided by contracted laboratories). However, the lack of interoperability and data exchange has significantly hampered the utility of these data to date. Depending on the ability to effectively exchange information and overcome other constraints, electronic medical record systems may not be capturing the data from multiple specialists who have rendered care to patients.

3. Patient-generated information (e.g., care experience, health and functional status). In addition to claims-based and clinically-enhanced data, other data are generated directly by patients. Examples of such data include patient assessments of care experience, patient understanding of care instructions/plans, and patient health and functional status. Such information is typically collected through surveys deployed in the clinical setting (e.g., functional status) or by other organizations. The Consumer Assessment of Healthcare Providers and Systems (CAHPS[®]) is the leading tool for measuring patient experience. It has been carefully constructed and tested, endorsed by the NQF, and nationally accepted by various stakeholders.

Efficient and effective data collection mechanisms are still being developed. While this information is largely collected through paper-and-pencil surveys today, alternative data collection methods – such as through electronic survey kiosks – are being tested to allow for quicker and less costly integration of data for care improvement and performance measurement purposes. Several large measurement initiatives targeting medical groups (e.g., through the Integrated Healthcare Association in California and Massachusetts Quality Partners) have been implemented through a collaborative data collection model and are yielding patientgenerated results at modest costs.

Standard Set of Measures

ACOs participating in the Brookings-Dartmouth ACO pilot program have agreed to implement an initial set of standardized measures that will be produced in a consistent fashion across all payers and sites. Several criteria were considered in selecting the starter measures. First, the program sought to identify a nationally consistent measure set based on widely accepted and endorsed measures that the vast majority of payers and providers are familiar implementing. Second, the measures should cover key aspects of primary care, preventive care, and chronic care services. Lastly, in recognition of the health IT infrastructure capability, the program agreed to rely on administrative data only for the computation of these measures, so that they could be implemented within the first performance year of any ACO. The thirteen measures in Exhibit 3.16 represent the starter set of measures that will be used across the pilot sites.

Each of the measures in the starter set can be computed using administrative data and has been endorsed by the NQF. Also, because these measures are part of the Healthcare Effectiveness Data and Information Set (HEDIS), payers are experienced in calculating them at the health plan level. This initial set of measures focuses on key aspects of primary care and chronic care management. In the future, this set will expand to incorporate measures that cover services more comprehensively across the care continuum and settings. For hospital quality performance assessment, there are several nationally recognized sources, including the Agency for Healthcare Research and Quality (HCAHPS[®] and Quality Indicators), the Centers for Medicare & Medicaid Services (Quality Measures Management Information System and Hospital Compare), the Hospital Quality Alliance, The Joint Commission, and Leapfrog. The program strives to integrate these measures into the expanded set of measures as these pilot sites mature.

Priority Areas ^{a/}	Initial Measures
Overuse	Use of imaging studies for low back pain
Overuse	Appropriate testing for children with pharyngitis
Overuse	Avoidance of antibiotic treatment for adults with acute bronchitis
Overuse	Appropriate treatment for children with upper respiratory infection (URI)
Population Health	Breast cancer screening
Population Health	Cervical cancer screening
Population Health	Colorectal cancer screening
Population Health	Diabetes: HbA1c management (testing)
Population Health	Diabetes: cholesterol management (testing)
Population Health	Cholesterol management for patients with cardiovascular conditions (testing)
Population Health	Use of appropriate medications for people with asthma
Population Health	Persistence of Beta-Blocker treatment after a heart attack
Safety	Annual monitoring for patients on persistent medications

EXHIBIT 3.16. STARTER SET OF MEASURES

^{a/} The priority areas identified by the National Quality Forum.

ACOs that are able to produce performance results and outcomes above and beyond the measures listed in the starter set are encouraged to do so.

The Brookings-Dartmouth collaborators also plan to build on the starter measures by implementing clinically enhanced performance measures, which rely on data gleaned from clinical data systems in conjunction with administrative claims data. Candidates for additional measures are listed in Exhibit 3.17. Prior to their full adoption, they will be tested to ensure computation is feasible and results are reliable and valid. The future phases will include outcome measures, measures covering non-ambulatory services, and measures addressing critical priorities such as patient engagement and care coordination. In addition to these quality measures, ACOs will benefit by including measures of health care utilization, such as inpatient length-ofstay, emergency room utilization, and use of generics. These measures can provide insight into potentially unnecessary use patterns that could be ameliorated with access management or chronic care management. As the health IT infrastructure of ACOs mature and more potentially useful measures become available, it will be necessary to ensure that required and optional performance measures are updated on a regular basis.

EXHIBIT 3.17. POTENTIAL ACO QUALITY MEASURES USING CLINICALLY ENHANCED DATA

Measure	Details
Diabetes Measures	HbA1C Control - Percentage of adult patients with diabetes who had HbA1c control (<8.0 percent).
	LDL Control - Percentage of adult patients with diabetes with most recent LDL-C <130 mg/dL; LDL-C <100 mg/dL.
	BP Control - Percentage of patient visits with blood pressure measurement recorded, for patients with diagnosed hypertension.
	Eye Exam - Percentage of adult patients with diabetes who received a dilated eye exam.
	Kidney Disease Screen - Percentage of adult patients with diabetes who had at least one test for microalbumin or who had evidence of medical attention for existing nephropathy.
	Aspirin Prophylaxis - Percentage of diabetes patients who are taking aspirin on a daily basis.
CAD Measures	Drug therapy for lowering LDL - Percentage of patients with CAD who were prescribed a lipid – lowering therapy.
	Aspirin Prophylaxis - Percentage of vascular disease patients who are taking aspirin on a daily basis.
CHF Measures	Persistence of Beta-Blocker Treatment after a Heart Attack - The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged alive, from July 1 of the year prior to the measurement year to June 30 of the measurement year, with a diagnosis of acute myocardial infarction (AMI) and received persistent beta-blocker treatment for six months after discharge.
	Beta-Blocker Treatment after a Heart Attack - The percentage of patients 35 years of age and older during the measurement year, who were hospitalized and discharged alive from January 1 – December 24 of the measurement year, with a diagnosis of AMI and received an ambulatory prescription for beta-blockers upon discharge.
	IVD: Blood Pressure Management - The percentage of patients 18 years of age and older who had blood pressure <140/90 mmHg.
	IVD: LDL-C <100 - Percentage of patients 18 years and older with IVD whose most recent LDL-C screening <100.
Hypertension Measure	BP Control - The percentage of patients 18-85 years of age who had a diagnosis of hypertension (HTN) and whose blood pressure (BP) was adequately controlled (<140/90) during the measurement year.

Population Health Measures	Advising Smokers To Quit - The number of patients in the denominator who responded to the survey and indicated they had received advice to quit smoking from a doctor or other health provider, during the measurement year.
	Discussing Smoking Cessation Medication - The number of patients in the denominator who responded to the survey and indicated that medication to assist with quitting smoking was recommended or discussed.
	Discussing Smoking Cessation Strategies - The number of patients in the denominator who responded to the survey and indicated that their doctor or health care provider recommended or discussed methods and strategies other than medication, to assist with quitting smoking.
	Childhood immunizations - Percentage of children two years of age who had four diphtheria, tetanus and acellular pertussis (DTaP), three polio (IPV), one measles, mumps and rubella (MMR), three H influenza type B (HiB), three hepatitis B, one chicken pox vaccine (VZV),four pneumococcal conjugate vaccines (PCV), two hepatitis A (Hep A), two or three rotavirus vaccine (RV) and two influenza (flu) vaccines by their second birthday. The last three were added in 2010.
	Adult Body Mass Index (BMI) Assessment - Percentage of patients 18-74 years old who had an outpatient visit and who had their BMI documented during the measurement year.
	BMI records / Children (WCC) - Percentage of patients 2-17 years old who had an outpatient visit with a PCP or PB/GYN and who had evidence of BMI percentile documentation, counseling for nutrition and counseling for physical activity during the measurement year. Because BMI norms for youth vary with age and gender, this measure evaluates whether BMI percentile is assessed rather than the absolute BMI value.
	Flu Shots for Adults Ages 50-64 - The percentage of patients 50-64 years of age as of September 1 of the measurement year who received an influenza vaccination.
	Influenza vaccine - Percentage of patients 65 years of age and older as of January 1 of the measurement year who received an influenza vaccination.
	Pneumovax vaccine - Percentage of patients with pneumonia, age 65 and older, who have ever received the pneumococcal vaccine.
	Medication reconciliation - Percentage of discharges from January 1 – December 1 of the measurement year for patients 65 years of age and older, for whom medications were reconciled on or within 30 days of discharge.

Establishing Performance Benchmarks and Targets

There are several ways to take performance metrics into account under an ACO accountability framework. Multiple models are currently in use around the country tying performance attainment to financial incentives. We have laid out a basic framework for linking the performance targets to shared savings based on the starter set of measures. These principles could be applied against the identified starter set of measures as well as additional, desirable performance measures that payers and ACOs find useful. The basic framework is described below:

- Each performance measure will have an associated threshold. A minimum level of performance attainment (e.g., achieving the 50th percentile of a national or regional distribution of provider performance) could be required to "earn" performance points, with more points earned based on how far the minimum threshold has been exceeded.
- A minimum number of points are needed across the performance measure set in order for the ACO to become eligible for shared savings. An ACO could achieve a sufficient number of points by significantly exceeding performance targets for most but not all measures.
- In addition to or instead of earning points by achieving certain performance levels, ACOs could also earn points by demonstrating significant improvement in their performance as compared to the last time their performance was measured. Because there are variations in current performance across ACOs, the use of improvement thresholds – such as reducing the gap between current and national benchmark performance by 10 percent – may be seen as more equitable by some.

Details on how performance measurement will be tied to bonus payments are being developed for the Brookings-Dartmouth pilot sites and will be discussed more broadly when additional information is available.

Performance Calculation

There are several issues that need to be considered when determining how to calculate quality measures in the ACO framework. Foremost, one needs to determine the eligible patient population for whom the ACO providers assume accountability for the costs and quality of care. In order to have reliable and valid results, a sufficient population size is required. Below discusses several considerations for performance measurement calculation, including patient attribution, performance period, sample size, composite measures, and risk adjustment.

Physician/Patient Attribution

Previously, we describe the patient attribution process which aligns patients with ACOs, and these patients become the basis for determining whether the cost benchmarks are met. The same population should be used to determine eligibility for quality measurement purposes.

It is possible that not all patients in the ACO would be included in each of the performance measurement calculations, as not all patients will have relevant conditions. Also, each measure may require a certain period of enrollment (e.g., a "lookback" period) in order to calculate the measure. Most of the performance measures in the starter set require access to at least a full year of data to determine if the quality criterion was met. However, some measures may require less time, such as the use of imaging studies for low back pain.

Performance Period

The same performance period should be used for evaluating the quality measures and the financial performance. For example, if financial performance is evaluated on an annual basis, quality measures should be calculated on the same annual basis as well. This will permit quality and cost of care to be evaluated together, helping to guard against reductions in costs that reflect stinting on care. Performance calculations should also be done periodically to verify data integrity and to ensure timely actions are taken when performance goals are not met.

Reliability (Sample Size)

While other factors, such as measurement error, can contribute to the issue of reliability, sufficient sample size is a major determinant. There are few hard and fast rules on an appropriate sample size, as different stakeholders have different comfort levels on margins of errors. For example, HEDIS measures are only publicly reported when a health plan has at least 30 observations for the denominator.

Several options are available for ensuring the sample size is sufficient to produce statistically valid measures, including not using measures with small populations, expanding the timeframe of the measures, or aggregating data at the ACO level for all participating payers. Not using certain measures has the drawback of throwing out data that could provide useful insights on the quality of care provided by ACOs. Expanding the timeframe can add to the sample size, but it would take longer for ACOs to observe changes in the quality measures.

Aggregating measures at the ACO level across payers involves summing up the numerators and denominators for each of the payers within an ACO. The ACO-level measure would be the basis for the comparisons to targets. In order to have a valid measure at the ACO level, it is essential that measures are calculated consistently across all payers and all provider groups participating in ACOs.

In considering whether to aggregate measures, particularly for bonus-payment determination purposes, providers and payers may choose to make the decisions on a measure-by-measure basis. That is, not all measures require aggregation across payers to reach the minimum sample size to be statistically reliable. Furthermore, ACOs may choose different aggregation rules depending on the market characteristics. For example, assume that an ACO contracts with three payers in the market with one payer having a dominant market share. In this scenario, the large payer may not need to aggregate its results, while the two smaller payers may need to aggregate in order to achieve statistically reliable results. Composite measures, which are discussed below, can also be used to deal with small sample size issues. In this case, a larger sample size is obtained by combining data from various measures.

Composite Measures

There are several ways to assess the value of the measure being used for performance determination. The simplest approach is to evaluate each measure separately in determining whether the benchmark is met. This means that each measure is given the same weight of importance.

One alternative is to rely on composite measures. Composite measures provide a comprehensive view of the overall quality of care delivered by combining individual measures into a single measure. Composite measures offer several advantages. It offers a simple way to identify and reward providers who are delivering high-quality care comprehensively. It also provides an easy way to rank provider performance.⁶ Furthermore, composite measures can improve the statistical reliability of quality measures, which is a particular problem when assessing care for small patient panels or relatively rare outcomes measures. In order for composite measures to not impede actionability, it is recommended that underlying details for all measures making up the composite be provided to ACO providers.

Risk-Adjustment

Risk-adjustment of measures takes into consideration the underlying risk and severity of the patients, and supports more equitable and consistent comparisons. Risk-adjusted measures can provide meaningful comparisons across different ACOs or over different periods for an ACO.

Since factors other than the quality of care rendered – such as patients' age, gender, severity of illness, and comorbid conditions – can affect patient outcomes, risk-adjusted measures allow the analysis to focus on the quality of care rendered and not the risk characteristic of the patient or mix of patients. However, since only measurable and reported risk factors can be accounted for, the extent to which data can be risk adjusted is limited.

It is critical for measures to be risk adjusted appropriately, especially when using national or regional "norms" to determine targets. ACOs should conform to the standard risk adjustment methodologies applicable to endorsed measures. Additional information on best practices for risk adjustment is provided in the Part 3 Appendix.

Validation of Measure Results

Validation should be incorporated into the quality measurement process. It is critical to ensure that both the payers and providers are confident in the measure results. Validation should ensure all calculations are done in accordance with technical specifications. Consistency in the implementation of data collection/aggregation methods will assist in evaluations of the effectiveness across various ACOs. Consistency also allows aggregating the measures to increase the sample size.

The validation process should ensure:

- Complete data are used in measure calculation;
- Programming algorithms are used accurately;
- Data checks (e.g., logic checks to identify if calculated results are plausible) are available; and,
- There is statistical precision and reliability.

A major component of data verification could be a full data audit. Audit ensures the validity of reported data and addresses data accuracy concerns. Audit programs typically assure the measure results for all parties are computed in accordance with predefined rules using comprehensive data.

Operationally, each ACO will need to determine how and who will be conducting the validation process, as well as verifying the measure calculation. One option is to rely on the payers to perform these functions for some of the measures. In Part 4, we discuss the pros and cons an ACO should consider in determining whether to perform these tasks in-house or to contract with an external vendor. Engaging a third party that is agreeable to both the payer and the ACO can alleviate concerns of gaming by either party. For ease of administrative burden, ACOs may want to standardize the processes of performance reporting and validation across different payers.

Public Reporting

A core ACO principle is to be accountable for the quality of care provided. As such, publically reporting the measures is a key aspect of implementing an ACO performance measurement program. Publically reporting the measures is intended to equip consumers with quality of care information that would help them make more informed decisions about their health care, while encouraging hospitals and clinicians to improve the quality of care provided to all patients.

Consistency is an important attribute of the measures to ensure that they are comparable across providers and understandable to consumers.

Quality Measurement in Other Reform Models

Quality measurement in accountability payment systems should send consistent signals to providers regarding priority areas for improvement. There is a wide range of payment reform initiatives, including expanded use of pay-for-performance programs and medical homes, as well as ACOs. Each of these requires the use of performance measures. Having consistent and standardized measures across these models will greatly assist in the evaluation and implementation of these programs. Consistency also needs to extend to incentive payments made by CMS to providers, in promoting the "meaningful use" of health IT, in particular EHRs. The use of consistent measures across these initiatives can help stimulate market-wide movement towards accountability payment reforms and accelerate improvement in the priority areas identified by the community. Consistency should also reduce the burden on providers and payers involved with participating in these initiatives.

THE "MEANINGFUL USE" REGULATION

The American Recovery and Reinvestment Act of 2009 includes the Health Information Technology for Economic and Clinical Health Act (HITECH), which established programs under Medicare and Medicaid to provide incentive payments for the "meaningful use" of certified EHR technology. The HITECH act will make up to \$27 billion available in incentive payments for EHR use until 2020.

On July 13, 2010, the U.S. Department of Health and Human Services (DHHS) released a final regulation defining "meaningful use" for EHRs to be applicable through 2012. The regulation includes multiple sets of clinical quality measures and requires providers serving Medicare and Medicaid beneficiaries to report on a minimum of: (1) three measures from their defined core set of measures, and (2) three measures from the additional set of clinical measures. There are an additional set of 15 quality measures required for eligible hospitals and critical access hospitals participating in Medicare and Medicaid programs. After 2012, the DHHS plans to require more advanced clinical measures. The current set of measures can be found at: http://www.ofr.gov/OFRUpload/OFRData/2010-17207_PI.pdf

ENDNOTES

1. There may be some providers in an ACO, such as anesthesiologists, that would not be used for attribution purposes. See Part 2 for more details on individual provider roles within an ACO, including those that would be most likely to be used for patient attribution or assignment.

2. Kautter J, Pope GC, Trisolini M, Grund S. 2007. Medicare Physician Group Practice Demonstration Design: Quality and Efficiency Pay-for-Performance. Health Care Financing Review. 29(1): 17-20.

3. We note that there are some emerging ACO initiatives involving Medicaid beneficiaries. For example, the Colorado Medicaid program is developing a regional accountability payment program. Also, the Patient Protection and Affordability Act included funding for a pediatric Medicaid ACO demonstration.

4. Other categories could include therapy (e.g., occupational therapy, physical therapy, and speech therapy) or home health services.

5. For information from the Quality Alliance Steering Committee on Data aggregation, please visit: http://www. healthqualityalliance.org/hvhc-project/data-aggregation-and-integration

 Shaller D, Sofaer S, Findlay S. Consumers and quality-driven health care: A call to action. Health Affairs. 2003;22(2):95-101.

Part 3 Appendix

Data and Health Care Analytics – Understanding Health Risk, Measuring Performance, and Assessing Opportunities for Improvement Dan Dunn



ACCOUNTABLE CARE ORGANIZATION

PART 3 APPENDIX: DATA AND HEALTH CARE ANALYTICS – UNDERSTANDING HEALTH RISK, MEASURING PERFORMANCE, AND ASSESSING OPPORTUNITIES FOR IMPROVEMENT

OVERVIEW

To assure chances of success, ACO managers will need sophisticated data and analytic tools in order to assess financial and clinical health risk, identify care opportunities, and to measure the cost and quality of the care delivered by the organization. These tools encompass a wide range of methodologies, and leverage different types of clinical and financial data. Assessing health risk, measuring performance, and assessing opportunities for improvement underpin the three key elements or principles of the accountable care model. Under the "local accountability" principle, risk assessment is applied to adjust the ACO spending benchmarks to reflect patient risks. Under the "shared savings" principle, ACOs need to understand the health risk of their patients, monitor the cost and quality of the care they receive, and find actionable opportunities for improvement to achieve savings. Under the "performance measurement" principle, measures of cost and quality and comparisons with benchmarks will be provided to payers, providers, and consumers.

Understanding member health risk will provide significant advantages for an ACO, as differences in risks across payers or groups of providers can impact contracting, budgeting, and the assessment of financial performance. Individuals generally do not select health plans and medical care providers randomly. Some members require more resources due to their health status and ACO or provider costs are affected by the particular combination of the risks patients represent. A key challenge for ACOs is to assess this risk across the organization and to adjust accordingly.

Assessing health risk can also facilitate coordination of patient care for an ACO. Many health care

organizations practice proactive care and case management, using various approaches to manage patients with a wide array of diseases and conditions. Accurately identifying higher-risk individuals and designing appropriate interventions can improve patient outcomes.

Measuring and improving medical care is an important focus for ACOs. Significant opportunities exist to improve the quality and efficiency of health care. Understanding the value delivered in health care and identifying and rewarding excellence are key steps in addressing these opportunities. These objectives can only be achieved through valid, actionable, and transparent health care measurement.

Increasingly, commercial payers, state agencies, and the federal government are evaluating the performance of physicians and hospitals. The same evaluations are applicable to ACOs. The results of these assessments are used in a number of ways. They include sharing findings with purchasers and consumers, offering incentives to providers, and rewarding best practices. There is increased interest in using performance measures to drive value-based payments and network design - with the federal government following a road map to link Medicare payments to the cost and quality delivered by providers and becoming a more active purchaser of higher quality and affordable care.1 Performing well against these standards provides the opportunity for an ACO to benefit financially and to distinguish itself as a high-performing and highvalue organization. Measurement can of course also be used to drive improvements in care and outcomes.

This appendix covers: 1) the analytic tools and methods used to address health risk assessment 2)

PART 3 APPENDIX | ACO TOOLKIT

the analytic tools and methods used to measure the cost and quality of care and 3) data and resources required to support these advanced analytics. Examples of the tools used in each area and their applications are provided.

UNDERSTANDING AND APPLYING MEASURES OF HEALTH RISK

Health risk can be defined as the expected health care costs or utilization of an individual or groups of individuals. Risk assessment is the measurement of that risk, linking the characteristics of an individual to their current and future resource use or clinical outcome. Risk adjustment is the mechanism that adjusts payment rates or measure results to reflect the differences in risks as measured by the risk assessment process. Risk assessment and adjustment tools have a number of applications for an ACO. They include setting payment rates more accurately, adjusting financial performance to reflect differences in population health status, measuring provider performance fairly across patient populations, and identifying high-cost patients for care management.

Basics of Risk Assessment Models

Models of health risk assessment vary along a number of dimensions, including the type of data required, the applications for which the models are being used, the modeling techniques, the outcomes to be measured, and the model outputs. Many risk models used in health care provide an assessment of cost or utilization outcomes for an individual – particularly when applied for financial analysis or rate setting. A number of health care models also have been developed that focus on specific patient events, such as the likelihood of an adverse event or mortality related to a clinical intervention. This section describes modeling approaches that are primarily used in assessing the risk of financial outcomes. The two basic components of most health risk models are risk markers and risk weights. Risk markers describe demographic clinical and other characteristics that distinguish one individual from another. Risk weights translate those markers into a measure of risk. Equation 1 below illustrates the basic structure of such a model. Risk is the measure of risk for individual i, Marker, describes the presence of risk marker m for individual i, and Wt_m is the weight assigned by the model to Marker m. The risk for an individual is the sum of the weights for all of their risk markers observed - often expressed as a relative score centered around 1.00, where 1.00 represents the average risk for a reference population. Using this approach, a risk score of 0.50 represents a level of risk one half of that average, a risk score of 2.0 twice that average, and so on. The risk for a group of individuals can be expressed as the average risk for all individuals in that group.

(1)
$$Risk_i = SWt_m^*Marker_i$$

Modeling and Data – Clinically-Based and Demographic Risk Models

Models of health risk assessment can be simple or guite complex. A demographic or age-sex model is an example of a simple model, where the markers describe the age and gender category for the individual and the weights represent the relative expected costs or resource utilization of individuals in that category. Demographic models are straightforward to administer, but offer little clinical information and perform poorly in terms of predictive accuracy for most applications (i.e., a demographic risk model does not predict costs well for an individual). Clinically-based models employ markers that leverage patient diagnoses and, in some cases, the use of medical services. In these models, the markers describe the presence of a clinical diagnosis or utilization event for an individual, and the weights represent

the incremental contribution to the risk of having that marker. Given the richness of the clinical information employed and the strong link between patient health status and expected resource use, the clinically-based models provide greater predictive accuracy, versus models using only demographic information.²

Many health risk assessment models leverage information readily available from administrative medical and pharmacy claims and enrollment data. Some models use clinical lab results, in particular where high-risk prediction is the objective. Models that employ pharmacy data or results from member surveys can also provide value when medical claims data are not available or incomplete.

Most risk models use data for a 12-month period to identify markers for an individual. The risk weight assigned to a marker is typically predefined by the model developer and can vary depending on the outcome being measured and available data. Software that encapsulates the health risk methodology and weightings is often employed to produce the risk assessment results. Relevant data are prepared and processed using the software to produce the risk scores by individuals and to develop information that is useful in understanding the measured risk.

Applications for Health Risk

In selecting a health risk assessment model, it is important to recognize the intended business use of the model. For example, risk assessment can be applied either retrospectively or prospectively. Both types of models have importance for ACOs. Retrospective or concurrent models use risk markers for an individual in a base year to measure risk for that same period of time. A prospective application uses markers in a base year to measure risk for a future time period. Retrospective models are most often used for comparing provider and health plan performance. Prospective models are often applied when setting payment rates and to stratify populations for care intervention and disease management.

The intended business use is an important consideration when selecting a model - using the right tool for the right purpose. As described above, prospective models are often applied when setting payments. The risk assessment model used by the Centers for Medicare & Medicaid Services (CMS) to reimburse health plans for serving Medicare beneficiaries is one example.³ Many state Medicaid programs use similar models.⁴ As a third example, an ACO's target benchmark may be risk-adjusted prospectively based on future risk expectations. In addition to being prospective, risk models used in payment most often include risk markers based on patient diagnoses and exclude markers describing utilization events. Where discretion is present, the risk assessment formula will not reward or penalize treatment decisions, such as the decision to admit a patient to the hospital, to perform a surgery, or to prescribe a medication. In this way, the payment systems provide appropriate incentives for medical practice.

A second business use for health risk assessment is high risk prediction. "Predictive models" are designed to identify patients of the highest risk in a population and to provide information useful in supporting care and health management. These models leverage all available, useful information – including diagnoses, history of medical service use, utilization events, and lab results – to identify patients who are expected to consume significant resources in the future and are good candidates for care management. As a result, these models provide enhanced predictive ability relative to models based exclusively on diagnoses.

Example – Assignment of Health Risks Using Three Different Models

A few examples can help illustrate how risk assessment models work and how they can be applied by an ACO. Table 1 summarizes the calculation of risk for three individuals using three

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different approaches to health risk assessment. The first two models are clinically-based and describe retrospective and prospective applications. The third model is a demographic-only, age-sex model. The risk markers observed for each individual are shown along with the weights assigned to each marker for each model. As shown, the clinical models use markers based on diagnostic information and also give some weight to age and gender in calculating prospective risk. The agesex model uses only the individual's age and sex to assess risk.

The first individual, a 58-year-old male, is observed to have diabetes, congestive heart failure (CHF), ulcers, and a dermatology condition. Each of these markers receives a numeric weight describing the contribution of that marker to risk.⁵ The sum of the weights across the markers observed is the risk score for the individual. The total risk scores of 6.632 and 6.741 for the retrospective and prospective applications suggest a level of risk for this 58-year-old male is more than six times that of the average individual in the reference population. The risk score based on the age-sex model provides a different assessment and is markedly lower than that for the clinical models. In an agesex model, all individuals in the category of male age 55-64 are assigned the same risk factor of 2.25, indicating that the expected cost of health care for individuals in this category is more than twice that of the average individual in the reference population. A comparison of these models suggests that using an age-sex model alone would likely underestimate their health risk. Finally, note that the retrospective and prospective risk scores for this example are similar, both driven by the presence of two chronic, ongoing conditions (diabetes and CHF) that comprise the majority of the patient's risk.

The calculation of risk for the second and third individuals can be interpreted in a similar manner. The observed difference between retrospective and prospective risk for the 35-year-old female illustrates the impact of an acute event (pregnancy) on the two clinical models. The pregnancy is a significant driver of expected costs for the current year, but has a negligible impact on risk for the future year.

Risk Marker	Retrospective	Prospective Bick	Age-Sex Risk		
Male, Age 58					
Insulin dependent diabetes, with co-morbidity	2.268	2.532	n/a		
Congestive heart failure, with co-morbidity	3.028	2.842	n/a		
Ulcer	1.231	0.606	n/a		
Lower cost dermatology	0.105	0.103	n/a		
Males, 55 to 64	0.000	0.658	2.250		
Total Risk Score	6.632	6.741	2.250		
Female, Age 14					
Asthma	0.352	0.360	n/a		
Lower cost infectious disease	0.066	0.045	n/a		
Females, 12 to 18	0.000	0.326	0.495		
Total Risk Score	0.418	0.731	0.495		
Female, Age 35					
Non-cranial nerve inflam, incl carpal tunnel	0.767	0.591	n/a		
Normal pregnancy, delivery	2.253	0.000	n/a		
Females, 35 to 44	0.000	0.326	1.224		
Total Risk Score	3.020	0.917	1.224		

TABLE 1. EXAMPLES OF THE ASSIGNMENT OF HEALTH RISK
Example – Applying Risk Adjustment to Capitation Payments

Table 2 provides an example of using risk results to adjust primary care capitation payments to medical groups. A base capitation rate of \$30 is assumed, an amount covering the cost per member for delivering monthly services related to primary care. Estimates of average relative health risk for the members assigned to each group are listed along with total membership. For this example, the the bottom of the table. The higher risk – and higher expected primary care costs – for Medical Group A resulted in an increase in payments, while the lower risks for Groups B and C resulted in a downward adjustment in payments.

Example – Predictive Model

Table 3 presents a final example, showing scores of individuals from a high-risk predictive model. An ACO may decide to further investigate the health status of these individuals and the care received, in

TABLE 2.	RISK	ADJUSTMENT	TO 9	SUPPORT	PRIMA	RY CARE	CAPI	TATION	PAYME	NTS

Risk Marker	Medical	Medical	Medical	All Groups
	Group A	Group B	Group C	
Relative Health Risk	1.150	0.950	0.900	1.000
Members	2,500	3,500	2,000	8,000
Base Primary Care Capitation Rate				
(Monthly)	\$30.00	\$30.00	\$30.00	\$30.00
Risk Adjusted Capitation Rate	\$34.50	\$28.50	\$27.00	\$30.00
Unadjusted Total Monthly Payments	\$75,000	\$105,000	\$60,000	\$240,000
Adjusted Total Monthly Payments	\$86,250	\$99,750	\$54,000	\$240,000

amounts have been adjusted to ensure the budget neutrality of the calculation (the same total dollars for all groups before and after the adjustment). As shown, the risk-adjusted capitation rate is the product of the group's relative health risk and the base rate. The adjusted and unadjusted total monthly payments for each group are presented at particular where gaps in care are also observed and actionable patient interventions can be applied. The primary risk drivers observed for each patient are also included. Most predictive models will provide information beyond individual risk scores, including a clinical profile, a summary of the key clinical drivers of risk, and information on opportunities for care.

Member	Relative Risk Score	Predicted Annual Cost	Primary Risk Drivers
Member A	87.50	\$218,750	Malignant neoplasm, lung
Member B	84.00	\$210,000	Chronic Kidney Disease, CHF, Diabetes
Member C	81.00	\$202,500	Hemophilia
Member D	74.50	\$186,250	CHF, COPD, Diabetes
Member E	71.10	\$177,750	Chronic Kidney Disease, Diabetes
Member F	68.20	\$170,500	Malignant neoplasm, bone
Member G	55.40	\$138,500	Neoplastic blood disease
Member H	54.35	\$135,875	CHF, Diabetes, Depression
Member I	52.00	\$130,000	Chronic Kidney Disease
Member J	45.00	\$112,500	Malignant neoplasm, GI system
Member K	44.50	\$111,250	CHF, Diabetes
All Members	1.00	\$2,500	

MEASURING PERFORMANCE – ASSESSING QUALITY AND COST OF CARE

Public awareness of quality issues and rapidly increasing costs have placed increased focus on measuring the quality and cost of health care, using measures that are meaningful, simple, and actionable (i.e., they can be used to drive improvement over time). Toward these ends, private payers, federal and state agencies, consumer groups, and even health care providers themselves have proposed, tested, and implemented a variety of measures to evaluate the quality and cost of health care. Understanding and performing well against these standards is critical for an ACO to achieve savings, meet quality improvement targets, and differentiate itself. Such measurement will also enable ACO managers to identify the referral physicians, hospitals, or other providers that provide high-quality and cost-efficient care and the groups that offer opportunity for improvement.

For most organizations, the primary objective in assessing performance is to identify quality care at a reasonable cost and delivered with good service. Cost of care describes the relative resources used in delivering health care or managing a patient's clinical condition. Quality is the assessment of clinical outcomes or the processes used in delivering patient care and their correspondence to evidence-based medicine and other treatment guidelines. Service can relate to patient satisfaction and access to care. Efficiency is the cost of care or resources required to deliver a given level of quality and service. This section focuses on the methods used to assess the quality and cost of care delivered by providers and organizations. Examples of how the results can be used to identify opportunities for improvement are provided. Methods to assess the quality of care are described first, followed by a discussion of cost measurement.

Measuring Quality of Care

There is a well-documented gap between current medical knowledge and actual health care practice – a number of studies have shown a correlation between compliance with care guidelines and proven treatments, and the outcome and/or cost of care.^{6,7,8,9,10} Across geographical regions, significant variation exists in the use of medical services without any evidence of improved outcomes, while health care costs continue to grow at a high rate nationwide.¹¹ The increasing push to pay for quality translates into purchasers, consumers, and patients requiring increased transparency regarding the quality delivered by physicians and hospitals.

Measuring and comparing the quality of care within an organization allows ACOs to:

- Identify both high-performing providers and areas where improved compliance with prescribed care is recommended;
- Identify diagnostic tests or treatments that are unnecessary or potentially harmful, with the ability to determine the pervasiveness of these tests in their populations;
- Identify care management opportunities, including "gaps" in care for patients and populations;
- Identify patients with indications of poor disease control, such as poor adherence to prescribed medication regimens; and
- Reduce potentially harmful drug-to-drug or drug-to-disease interactions.

A broad range of quality measures are currently available in the public domain, covering a range of measurement areas such as prevention, disease management, medication adherence, and patient safety. These measures support assessments of care for both chronic and acute patients and for a range of conditions covering the breadth of clinical medicine. As further investment is made and as electronic clinical data become more widely available, quality measurement is likely to grow in a significant way. Below highlights some of the key issues and challenges involved with quality measurement.

Challenges and Progress in Measuring Quality of Care

Efforts to measure health care quality in the United States have historically faced considerable challenges. These challenges include limited agreement on the standards used to measure care, the need to identify valid and available data sources to support measurement, and the lack of tools that incorporate robust and adaptable sets of measurement criteria to assess compliance.

More recently, progress has been made to address these challenges. Technology is better, metrics are improving, and national programs dedicated to the development of quality measures have grown.¹² Quality standards and metrics are derived from published, peer-reviewed literature, as well as guidelines from medical specialty organizations and national quality organizations. Many physician specialty organizations are participating in initiatives to develop quality measures. Endorsing organizations such as the National Quality Forum (NQF) are playing a significant role in setting the standards for measurement.

The information available to support measurement also has improved. Administrative or transaction data – including medical and pharmacy claims, and selected clinical data such as laboratory results – have increased in both availability and comprehensiveness, thus providing a rich and convenient information source from which organizations can evaluate health care. Significant investment is being made to standardize medical records and other electronic clinical data, thereby increasing access to this information – a key source for valid measurement. Equally important, tools and technology exist that encode standards of care and provide an efficient and robust way to assess care compliance against these standards.

Process Measures and Outcome Measures

Most measures of health care quality can be categorized as either process measures or outcome measures. Process measures compare the care received by a patient with that indicated by research-based standards, with the idea that increased compliance with these standards will lead to better patient outcomes. For example, for patients with diabetes, process measures include¹³:

- HbA1c Testing an HbA1c test performed for the patient during a 12-month measurement period (measurement year);
- Eye Exam an eye screening for diabetic retinal disease by an eye care professional within the measurement year; and
- LDL-C Screening an LDL-C test performed during the measurement year.

Outcome measures describe the clinical status of a patient or a clinical result, again reflecting published guidelines and standards of care. Increased patient functionality and quality of life can also be used as a measure of outcome. Examples of outcome measures for diabetes describing clinical status include:

- Good HbA1c Control the most recent result for an HbA1c test for the patient during the measurement year is < 7.0 percent;
- LDL-C Control the most recent result for an LDL-C test for the patient during the measurement year is < 100 mg/dL (threshold 1); and
- **BP Control** the most recent blood pressure reading for the patient during the measurement year is < 130/80 mm Hg.

Implementing Measures of Quality and Applying Results

Quality measures are typically implemented using either commercial software that encodes the measure specifications or internallydeveloped computer programs that capture these specifications. The data used to support quality measures include member enrollment data, administrative medical and pharmacy claims, encounter data, lab results, and information from medical records. The data is collected and integrated by the user and processed using the packaged software or program code. Outputs include the compliance results of each measure for each individual and information summarizing the details behind the measurement.

ACO managers can use the quality measurement results to support analysis at the organization, provider, or patient level. At the ACO level, reports can highlight the organization's best opportunities for quality improvement by identifying the areas with the lowest guideline compliance. At the patient level, quality results can be used by providers and case managers to identify care opportunities and insights for patient education.

At the provider and provider group level, guality measurement can involve a number of steps. As a first step, patients and quality measures are attributed to those providers most responsible for patients' care. Attribution is a key step in valid quality measurement and can be performed in different ways - the approach often depends on the providers being measured. For example, for primary care physicians, a wide range of measures can be attributed to the physician who is responsible for managing the patient's care. For specialists, attribution may focus only on patients and measures where the specialist contributes significantly to the relevant care (e.g., an endocrinologist observed to provide the majority of diabetes care to a patient over some period of time.) For surgeons, the physician performing the procedure can be deemed responsible. Finally, the same quality measure

is often attributed to more than one provider, recognizing the importance of care coordination and the fact that for many patients, multiple physicians contribute to their care.

Once attribution has been done, the provider's results can be summarized at various levels, such as across measures for a particular condition or across all measures and patients. Results are often compared with internal and external benchmarks, such as a target level of compliance or the average results of the provider's peers.

Examples of Quality Measurement Results

Table 4 provides an example of a report for an individual physician, summarizing the level of compliance with the treatment protocols prescribed for diabetes. A similar report could be created by the physician group or for all patients covered by the ACO. Eight measures are included in the example. The table lists a description for each of the measures and a clinical synopsis of the measure guideline.¹⁴ It shows the level of compliance for each of the measures for the patients attributed to "Dr. Smith." As a comparison, the levels of compliance for the same measures for the other internists in the ACO are shown, along with the ratio of Dr. Smith's performance relative to his peers. The last row of the table provides a composite result for Dr. Smith across all patients and measures.¹⁵ The value in this row for "% Peer Compliance" reflects the composite result for Dr. Smith's peers if they had the same mix of opportunities across the eight measures as was observed for Dr. Smith.¹⁶

The results indicate that Dr. Smith's level of compliance for these measures is somewhat less than his peers within the ACO, with the greatest discrepancies observed for HbA1c testing and screening for nephropathy and retinopathy. The ratio of Dr. Smith's overall compliance rate (64 percent) to that of peers (74 percent) was 0.87, indicating compliance 13 percent below peers. A list of Dr. Smith's patients for whom compliant care was not observed could accompany this report.

MEASURES
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TABLE 4.

Dr. John Smith, Internal Medici	ine, Medical Group A					
	Mooning Summin	# of Occordination	Compliance	%	% Peers	Compliance Relative to
Patient(s) that had at least 2 HbA1c tests in last 12 reported	HbA1c monitoring is recommended for all patients with DM.	200	06	45%	%09	0.75
months.						
Patient(s) that had an annual	Annual screening for diabetic nephropathy		C	1001	1011	010
screening test for diapetic nephropathy.	is recommended unless climical exclusion criteria have been met.	2002	οΩ	40%	%cc	0./3
Patient(s) that had an annual screening to diabetic	Annual screening for diabetic retinopathy is	002	60	46%	62%	0 74
retinopathy.	been met.		}			
Adult(s) with a LDL cholesterol	Management of LDL cholesterol goal is					
test in last 12 reported months.	recommended for adults with DM. This	200	160	80%	85%	0.94
	should be checked annually at minimum.					
Adult(s) with most recent LDL result < 100mg/dL.	A LDL cholesterol goal of < 100 mg/dl is recommended for adults with DM. <70mg/	80	65	81%	%06	0.90
	dL is a therapeutic option in some patients.					
Patient(s) taking an ACE-	Patients taking ACE-inhibitor or angiotensin					
inhibitor or angiotensin II	II receptor antagonists should have, at a					
receptor antagonist that had a	minimum, annual testing of specific serum	95	75	79%	91%	0.87
serum potassium (K+) in last 12 reported months.	parameters.					
Patient(s) that had an office	Patients with DM should have appropriate					
visit for diabetes care in last 6	access to care including, at a minimum,					
reported months.	assessment by a physician every 6 months. Patients with subortimal diabetic control	200	190	95%	%06	1.06
	can be identified for additional interventions.					
Patient(s) with evidence of	Patients with evidence of specific					
specific diabetic complications	diabetic complications would benefit from					
that had endocrinology	endocrinology consultation within 6 months.	30	22	73%	83%	0.88
consultation in last 6 reported						
months.						
All Measures	Composite of all measures for Diabetes	1,205	774	64%	74%	0.87

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Measuring Cost of Care

The cost of care is another important area of focus for ACOs in measuring performance. There are a number of steps involved in measuring costs. These steps are described generally in Table 5. above. Ideally, the measures should be meaningful (i.e., they are reflective of the health care services being measured), simple, and actionable (i.e., they can be used to drive improvement in patient care over time).

Measurement objectives and strategy	Identify the goals of measurement and how the results will be used.
Data preparation	Collect, standardize, and integrate information to support measurement, including enrollment, medical and pharmacy service data, and clinical records from lab results and other sources.
Units of measurement	Select and create the units of measurement, including per episode of care, population-based, per inpatient admissions, or specific procedures.
Providers to be measured	Select the physicians and hospitals to be compared and create "peer groups" for use in comparisons – typically defined using attributes such as hospital type, physician specialty, and location.
Scope of measurement	Identify the scope of measurement for each peer group; for example, the medical condition categories for a group of specialists.
Attribution	Assign patients and episodes to individual providers and groups.
Metrics	Identify the metrics for use in comparisons, such as overall costs, costs by type of service, or the utilization of specific services.
Risk or case mix adjustment	Adjust for differences in patient morbidity or case mix across providers
Communication and improvement	Create physician and hospital results and share these findings with providers and other stakeholders. Use the results to drive improvements.

TABLE 5. KEY STEPS IN MEASURING COST OF CARE

Some of the steps outlined above warrant further discussion.

Measurement Objectives and Strategy

Identifying the measurement objectives is a key consideration for all steps, including selecting a measurement approach, the providers to be measured, and the metrics to be applied. Most importantly, an ACO should assess how the information will be used – whether it is to differentiate the organization, improve financial performance, enhance patient care, or all of the Given the central role of physicians and hospitals in measurement, methods and measure results will need to be understandable and transparent to providers. Working with providers to obtain consensus on methods and their intended uses is a key step.

Units of Measurement

The unit of measurement should be aligned with the measurement objectives. Below we discuss how several different types of units can provide insights on the effectiveness of health care delivery.

Per Capita Measures. Population, or per capita, measurement is one approach and presents the most complete picture for members served by an ACO or a provider. Examples of these measures are cost per member per month (PMPM), cost per patient per month (PPPM), and inpatient admissions per 1,000 per year. One advantage of population-based measures is the ability to capture all of the services for a defined population, across all providers and conditions treated. This type of measurement is most meaningful where the measured entity has clear responsibility for a significant portion of a patient's care. Health plans, provider-hospital organizations, ACOs, and primary care physicians are examples. This approach can also have advantages for patients with certain chronic conditions, such as diabetes, for which the management of a wide range of co-morbidities is of central importance in delivering good care.

Episode Measures. Some of the advantages of population-based measures also create challenges for their use. In particular, patients often present with a number of different acute and chronic conditions – many occurring during the same period of time. Patients can also have multiple care providers, each contributing to the same or different conditions. Assessing the cost of care related to a condition or the performance of physicians who focus on a certain area of medicine requires a different approach – an approach that identifies conditions. Episodes of care accomplish this and support the measurement of providers on those parts of care for which they are most responsible.

An episode of care can be characterized as a condition classification methodology that combines related services into a medically relevant and distinct unit describing a complete episode. An episode defines a unique clinical condition for a patient and the services involved in the diagnosis, management, and treatment of that condition. In addition to grouping individual services to unique episodes, these methodologies also characterize episodes from a clinical perspective, including the conditions identified. Most methodologies will further differentiate episodes based on the presence of significant complications and/or co-morbidities, some assigning a level of severity to each episode. This approach enables more accurate case-mix adjustment and valid comparisons across patients and providers. Episodes of care describe a wide range of acute and chronic conditions. Examples include hypertension, diabetes, CHF, pregnancy, leukemia, spinal trauma, and minor infectious diseases.

In addition to condition-based episodes, some methodologies provide a narrower focus – they assess the services involved in delivering surgical procedures. These methodologies have value in evaluating performance around procedural care, including assessing the resources used by surgical specialists. Examples of procedural episodes include coronary artery bypass graft (CABG), knee replacement, and cataract surgery.

Most episode-of-care methodologies will determine completion and outlier status for an episode. In order to identify a complete episode, methodologies review the timing of the episode services and frame the episode by a start date and an end date, often using a clean period that notes the absence of patient care related to the episode. Assessing the completeness of an episode is most important for acute conditions, which by nature will have a beginning and an end. Chronic episodes can be assigned a start date where relevant care is first observed. However, these episodes will continue and are often parsed into annual intervals going forward to define "complete" episodes for analysis. Table 6 provides a simple example of an acute episode of care and how episodes are built.

Patient Treatment	Measured Disease Episode
1. Patient presents a specific complaint.	Episode begins with a service denoting a clinician has evaluated the patient and determined the types of services required to further identify and treat his or her condition.
2. One or more physicians provide tests and treatment.	Episode accumulates additional records, tied to the first claim by clinical logic identifying specific diagnosis or procedure codes.
3. Patient recovers and does not seek physician care related to the same condition again for some time.	End of episode.

TABLE 6. RELATING PATIENT TREATMENT AND AN EPISODE OF CARE

Determining if episodes are cost outliers is typically conducted by comparing observed costs for an episode with assigned lower and upper bounds that frame the normal range of costs. Episodes with costs beyond this range are flagged as outliers. Outliers can be the result of inappropriate treatment; rare, extremely complicated cases; or simple data or coding errors. The use of complete, non-outlier, severity-adjusted episodes in health care analytics supports valid and consistent comparisons.

Episode methodologies are delivered in the form of grouper software that accepts administrative enrollment and claims data and assigns individual medical and pharmacy services to unique episodes of care. Outputs include details on the mapping of each service into a unique episode and an episodelevel summary describing the clinical condition, episode severity, and other key information. Given the potential complexity of these methodologies, a key consideration in selecting an approach is the transparency around the details of the methodology, such as the measurement specifications, the clinical rules, and the supporting output. Sufficient transparency is necessary to support an in-depth understanding of the episode results. The results from applying episode-of-care tools can support ACO managers in achieving a number of insights about their organizations:

- Track ACO performance and cost trends around specific diseases and episodes;
- Track the prevalence of conditions overall and by severity – and the key services involved in diagnosing, managing, and treating those conditions;
- Track episodes and trends by population groups, including payer, geographic area, and provider organization;
- Provide valid measures and comparison of providers based on cost of care; and
- Improve understanding of disease-specific risk to enhance care and case management.

Inpatient Admission Measures. In addition to using populations and episodes as units of measurement, assessing the cost of services provided in the context of an inpatient admission offers another opportunity for an ACO. Grouping the services provided by a hospital into a unique inpatient stay is relatively straightforward. The detailed inpatient hospital claim records can be identified and used to create a single record summarizing the inpatient admission. These units can be further categorized by case-mix, using systems such as Diagnosis-Related Groups (DRGs). These systems use available diagnostic and procedural information and assign a DRG to the inpatient stay, describing the clinical nature of the admission, the level of severity and the presence of a significant procedure. DRGs are used widely to support inpatient hospital payment, including the Medicare program. DRGs provide a useful tool for an ACO to case-mix adjust the cost and utilization data when comparing across hospitals.

Attributing Measures to Providers

Attributing patients and episodes to the appropriate physicians and groups is a challenging step in cost measurement. Over some period of time, a patient can have multiple conditions and, in many cases, multiple providers caring for the same condition. For example, for an episode of hypertension, a patient can be managed by their primary care physician, an internist, and also receive services from a cardiologist. For a patient with coronary artery disease, an internist, a cardiologist, and a surgeon can all play a key role in providing the patient's care. A methodology is required to identify these episodes for a patient and the providers responsible for the services performed within episodes.¹⁷

Most attribution approaches can be categorized as activity-based or population-based. An activitybased approach attributes a patient or episode to the provider(s) responsible for the greatest amount of activity during the course of the episode. Activity can be measured using different concepts, including the cost of services rendered by a provider, episode clusters owned, or patient visits. "Sufficient" evidence of the provider's responsibility for the episode is usually required (e.g., attribution only taking place where a provider is responsible for 30 percent or more of the physician encounters during the episode.) This approach prevents providers from "winning" episodes where they have a small amount of involvement relative to their peers or all physicians involved in the episode. Activity-based approaches are often used in performing attribution for specialist physicians or for primary care physicians where a gatekeeper, or panel-based, model is not in place.

Population-based attribution assigns measures to the provider who is responsible for the member's episodes – whether or not the provider rendered any of the services during those episodes. Populationbased approaches are used where the measured entity has clear responsibility for managing all, or significant components, of a patient's care. Primary care physicians in a gate-keeper model would be one example of this approach.

Case-Mix or Risk Adjustment

Measures of the cost of care for an ACO or its providers can be impacted by the underlying risk and severity of the patients enrolled or managed. Case-mix or risk adjustment addresses these differences and supports more consistent and equitable comparisons. These approaches allow a focus on differences in resource use deriving from differences in the practice of medicine rather than differences in the mix of episodes or patients.

Each of the units of measurement described above – populations, episodes, and inpatient admissions – have methodologies available to support good case-mix and risk adjustment. For populations, an ACO would adjust the measures using the health risk assessment tools described above. For episodes of care, systems that assign levels of severity to an episode or classify episodes based on the presence of complications and co-morbidities can be used directly to support case-mix adjustment. For inpatient admissions, DRG casemix classification systems serve the same purpose.

Examples of Cost of Care Measurement Results

Table 7 provides an example comparing the cost of care performance of two cardiologists

using episodes of care. The analysis uses only complete, non-outlier condition episodes for CHF, hyperlipidemia, hypertension, and ischemic heart disease. The upper section of the table summarizes results at the condition and severity level. A higher severity level for a condition indicates the presence of one or more complications and/or co-morbidities that impact the resources required for treatment. The middle section in the table summarizes results for each of the conditions across all severity levels. The findings for each physician across all episodes are presented at the bottom of the table.

Table 7 shows the number of episodes attributed to the cardiologist, the observed cost per episode, peers' cost per episode (the "expected" amount), and the ratio of the cost per episode for the cardiologist to his peers. By condition and severity level, the peers' cost per episode is the average experience of all cardiologists included in the measurement for those episodes. The peers' experience is case-mix adjusted and assumes the same mix of episodes (by condition and severity) as the physician being measured. Notice that for the overall summary, the peers' cost per episode for Dr. Jones is \$3,207, while that amount for Dr. Smith is \$3,317. The higher amount for Dr. Smith indicates a higher case-mix and greater expected costs relative to Dr. Jones. These peer amounts, adjusted for the specific mix of episodes observed for the physician being measured, capture the casemix adjustment appropriate for the analysis.

In the last column, a relative cost ratio less than 1.00 indicates that the observed cost per episode for the physician is less than his peers. As shown, both the cardiologists' costs per episode are below their peers, on an overall basis, and for most of the categories shown. An additional report using the same measure information could summarize results by type of service, or specific utilization such as the use of a specific diagnostic test or treatment, providing greater insights into the factors behind differences in resource use.

TABLE 7. EXAMPLE OF PHYSICIAN COST OF CARE REPORT, EPISODE BASED

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Condition and Severity Level	Number of Episodes	Observed Cost per Episode	Peers' Cost per Episode	Relative Cost of Care Ratio
Dr. Jones		By Condition	n and Severity L	.evel
CHF, Level 1	10	\$1,016	\$1,354	0.75
CHF, Level 2	8	\$1,383	\$2,128	0.65
CHF, Level 3	6	\$1,477	\$3,283	0.45
Hyperlipidemia, other, Level 1	22	\$348	\$536	0.65
Hypertension, Level 1	35	\$825	\$687	1.20
Hypertension, Level 2	22	\$1,262	\$949	1.33
Hypertension, Level 3	16	\$885	\$1,106	0.80
Hypertension, Level 4	12	\$1,044	\$1,492	0.70
Ischemic heart disease, Level 1	50	\$3,549	\$3,622	0.98
Ischemic heart disease, Level 2	24	\$6,547	\$6,356	1.03
Ischemic heart disease, Level 3	14	\$11,308	\$16,154	0.70
Dr. Smith		By Condition	n and Severity L	.evel
CHF, Level 1	15	\$1,422	\$1,354	1.05
CHF, Level 3	6	\$2,659	\$3,283	0.81
Hyperlipidemia, other, Level 1	30	\$590	\$536	1.10
Hypertension, Level 1	35	\$550	\$687	0.80
Hypertension, Level 2	84	\$835	\$949	0.88
Hypertension, Level 3	21	\$874	\$1,106	0.79
Hypertension, Level 4	3	\$1,790	\$1,492	1.20
Ischemic heart disease, Level 1	120	\$3,803	\$3,622	1.05
Ischemic heart disease, Level 2	64	\$3,877	\$6,356	0.61
Ischemic heart disease, Level 3	12	\$12,923	\$16,154	0.80
Ischemic heart disease, Level 4	3	\$40,419	\$26,946	1.50
Dr. Jones		Ву	Condition	
CHF	24	\$1,254	\$2,094	0.60
Hyperlipidemia	22	\$348	\$536	0.65
Hypertension	85	\$980	\$947	1.03
Ischemic heart disease	88	\$5,601	\$6,361	0.88
Dr. Smith		Ву	Condition	
CHF	21	\$1,776	\$1,905	0.93
Hyperlipidemia	30	\$590	\$536	1.10
Hypertension	143	\$791	\$919	0.86
Ischemic heart disease	199	\$4,929	\$5,609	0.88
Dr. Jones			Overall	
Overall	219	\$2,804	\$3,207	0.87
Dr. Smith			Overall	
Overall	393	\$2,924	\$3,317	0.88

Cardiology, Medical Group A

DATA AND RESOURCES REQUIRED TO SUPPORT HEALTH CARE ANALYTICS

A remaining challenge for an ACO is to put the health care analytics into practice, including integrating the required data to support the analytics and identifying the solutions available to support their applications.

Complete and consistent data is critical in supporting valid measurement. Many of the concepts described in this chapter require a full record of the health care experience for the individuals and the populations being measured. For example, to assess compliance with diabetes process measures, complete medical and pharmacy claims are needed to identify diabetics and to capture the performance of an indicated nephropathy or retinopathy screening test or the prescription of an ACE-inhibitor. Accurate identification of episodes of care also will benefit from complete information. ACOs may have more direct access to the medical and pharmacy data or clinical lab results for those services delivered by the physicians and hospitals that participate in the ACO. However, many of these methods described above will require information beyond those services delivered by the participating providers, such as the medical and pharmacy services delivered by non-ACO providers. ACOs under different organizational structures are likely to encounter different issues with data accessibility, data completeness, and data accuracy. In general, partnering with commercial and public payers to obtain more complete information is an important step.

The data used to support measurement also require accuracy and consistency around key data elements. In general, diagnosis and procedure codes are available from administrative claims and encounter data. The financial amounts required to support cost measurement are also typically available from claims data. The assessment of certain quality outcomes can be supported by clinical lab results. These data will need to be reported using appropriate standards, including the codes used to identify lab tests and the metrics used to report results. A process needs to be in place to validate and test the reasonableness of the data to ensure data integrity. Missing data, incomplete data, and coding errors would potentially affect the accuracy of the measurement results. (Some of the analytic software have builtin processes to identify data completeness and validity issues.)

Once the data have been integrated and prepared, the next step involves the application of the health care analytic methodologies. A number of the risk assessment and measurement approaches use a wide range of algorithms and weightings to score patients, to group episodes and to assign patient and episode severity. In some cases, an ACO could develop an understanding of a measure specification and create internal capacity to apply the methodology. However, many of these methodologies are complex. They require ongoing maintenance and recalibration to reflect changes in measure specifications and updates for new diagnosis and procedure codes. As a result, most users of health care analytics select an external application or vendor to assist them with the measurement task.

In general, the tools available to support health care analytics are delivered in the form of a software engine. These engines encapsulate the analytic methodologies and specifications. The software accepts administrative and clinical data and uses the information to produce measures of risk, quality results, or episodes of care. The output typically includes a data mart, reports describing the results, and supporting information to assist the ACO in understanding the findings. Some applications also will provide static and dynamic reports to allow additional analysis and to support internal and external communication of findings. There are a number of analytic and software vendors available to support ACOs in implementing health care analytics. Table 8 provides a sample of these companies and methodologies, organized around the analytic concepts discussed in this section.

SUMMARY

Health care analytics is an important area of focus for ACOs. Measures of health risk across the organization enable more accurate financial analysis and contribute to better coordination of patient care. Assessing the cost and quality of the care delivered by an ACO presents another opportunity. Increasingly, private and public payers are evaluating physician and hospital performance and using the results in a number of ways, including public reporting, care improvement, and as a basis for encouraging and rewarding best practice. Performing well against measurement standards provides an opportunity for an ACO to benefit financially and to distinguish itself as a high-value organization. Actionable measure results can also be used to drive opportunities for improvement.

Table 8. HEALTH CARE ANALYTICS METHODOLOGIES

There are a number of analytic and software vendors available to support ACOs in implementing health care analytics. The table below provides a sample of these companies and methodologies, organized around the concepts discussed in this section. In addition to a description of the methodology and the company, a website address is provided to obtain further information.

Health Care Analytic Methodologies

I. Health Risk Assessment and Predictive Modeling					
Methodology (Company)	Description				
Adjusted Clinical Groups (CSC)	The Johns Hopkins Adjusted Clinical Groups (ACG) Case-Mix System includes solutions for a number of applications, including population-based health risk assessment and predictive modeling. The ACG Rx Predictive model supports risk measurement using only pharmacy data (http://acg.jhsph.edu/).				
Chronic Illness and Disability Payment System (University of CA, San Diego)	The Chronic Illness and Disability Payment System (CDPS) is a population-based risk model developed to support Medicaid applications. The Medicaid RX (MRX) model supports risk measurement using only pharmacy data (http://cdps.ucsd.edu).				
3M™ Clinical Risk Grouping Software (3M)	The 3M Clinical Risk Grouping Software (3M CRGS) supports prediction of health care utilization and costs on a prospective and retrospective basis (http://www.3Mhis. com).				
DxCG (Verisk)	The DxCG system includes solutions for a number of applications, including population-based health risk assessment and predictive modeling. The DxCG Pharmacy models support risk measurement using only pharmacy data (http://www.veriskhealth.com).				
Episode Risk Groups (Ingenix®)	The Symmetry Episode Risk Group® (ERG) application supports prediction of health care utilization and costs on a prospective and retrospective basis. The Symmetry Pharmacy Risk Groups [™] (PRG) model supports risk measurement using only pharmacy data (http://www.ingenix.com/ProductList/R/T/).				
Impact Pro (Ingenix®)	Impact Pro [™] is a predictive modeling suite that supports solutions for a number of applications, including high risk prediction, care management, and underwriting (http://www.ingenix.com/ProductList/R/T/).				
Risk Navigator Clinical (MEDai)	Risk Navigator Clinical® is a predictive modeling suite that supports solutions for a number of applications, including high risk prediction, care management, and underwriting (http://www.medai.com).				

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II. Quality Measurement					
Methodology (Company)	Description				
ActiveHealth Management®	ActiveHealth Management applications encapsulate quality measure specifications and support results on quality compliance at the patient and measure level (http://www.activehealthmanagement.com).				
EBM Connect (Ingenix®)	Symmetry EBM Connect® encapsulates quality measure specifications and support results on quality compliance at the patient and measure level (http://www.ingenix.com/ProductList/R/T/).				
Resolution Health™	Resolution Health applications encapsulate quality measure specifications and supports results on quality compliance at the patient and measure level (http://www.resolutionhealth.com).				

Health Care Analytic Methodologies

Health Care Analytic Methodologies

III. Episodes of Care	
Methodology (Company)	Description
Episode Treatment Groups (Ingenix®)	Episode Treatment Groups® (ETG) creates episodes of care for a patient by identifying a unique clinical condition and the services involved in diagnosing, managing, and treating that condition. The Procedure Episode Groups [™] (PEG) methodology creates episodes of care in the context of a surgical procedure (http://www.ingenix.com/ProductList/R/T/).
Medical Episode Grouper (Thomson Reuters)	Medstat Medical Episode Grouper® (MEG) creates episodes of care for a patient by identifying a unique clinical condition and the services involved in diagnosing, managing, and treating that condition (http://home.thomsonhealth care.com).

ENDNOTES

1. An overview of the key projects, programs and demonstrations being conducted by the Centers for Medicare & Medicaid Services (CMS) can be found in "Roadmap for Implementing Value Driven Health care in the Traditional Medicare Fee-for-Service Program," available at: http://www.cms.hhs.gov/QualityInitiativesGenInfo/downloads/VBPRoadmap_OEA_1-16_508.pdf.

2. A good health risk assessment model should maximize predictive accuracy (i.e., how close actual levels of costs or utilization are to those predicted by the model). However, depending on the application, other factors should be considered, including clinical relevance, incentives for efficient and quality care, administrative practicality, and ability to restrict manipulation and gaming.

3. Pope GC, Kautter J, Ellis RP, Ash A, Ayanian JZ, Iezzoni LI, Ingber MJ, Levy JM, Robst J. Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model. Health Care Financing Review, Summer 2004, Volume 25, Number 4, pp 119-141.

4. Kronick R and Llanos K. Rate Setting for Medicaid Managed Long-Term Supports and Services: Best Practices and Recommendations for States, Center for Health Care Strategies, March 2008.

5. The weights for these models are typically estimated using databases describing the experience of a large population of individuals.

6. Crossing the Quality Chasm: A New Health System for the 21st Century. Institute of Medicine, Committee on Quality of Health Care in America. Academy Press, 2001.

7. Institute of Medicine Committee on Quality of Health Care in America. To Err is Human: Building a Safer Health System. The National Academies Press; 1999.

8. McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristofaro A, Kerr EA. The Quality of Health Care Delivered to Adults in the United States. N Engl J Med. 2003;348:2635-45

9. Osterberg, L and Blaschke, T. Adherence to medication. N Engl J Med 2005;353:487-97.

10. McDonald, HP, Garg, AG, and Haynes, RB. Interventions to Enhance Patient Adherence to Medication Prescriptions. JAMA 2002; 288:2868-2879.

11. Wennberg, John E, and Cooper, MM, eds. The Dartmouth Atlas of Health Care in the United States. Chicago: American Hospital Publishing, Inc., 1998.

12. Examples of these programs and organizations include the American Medical Association Physician Consortium for Performance Improvement (PCPI), CMS Physician Quality Improvement Initiative (PQI) and National Committee for Quality Assurance (NCQA).

13. HEDIS 2009 Specifications for Physician Measurement, NCQA, 2008.

14. Measures and measure synopses are from Symmetry EBM Connect ®. http://www.symmetry-health.com.

15. The composite result for Dr. Smith is based on an "opportunity-weighted" design, where each measure opportunity is weighted equally. Alternatively, opportunities for different measures could be weighted differently, reflecting clinical importance, strength of evidence for a measure, or the objective of an ACO to drive improvement in certain processes and clinical areas.

16. A measure of statistical significance could be applied to the comparison of the physician's results versus peers. Such a test would account for the number of opportunities (sample size) available for the physician and the observed variation in compliance for a measure or mix of measures.

17. The approach used for attributing patients and episodes to providers must be defensible, understandable and accepted by all stakeholders. It must be supported by readily available information and be robust across applications – working well for different sources of data, patient populations and over time. Flexibility in choosing an approach also has importance, giving consideration to the characteristics of the specialists being compared and to the nature and severity of their patients and episodes.

Part 4

ACO Infrastructure John Bertko, Paul Katz, Bob Power



ACCOUNTABLE CARE ORGANIZATION

PART 4: ACO INFRASTRUCTURE

For an ACO to successfully deliver the level of integrated and efficient care that would allow it to achieve shared savings, it must have the appropriate resources to effectively carry out care delivery functions. It also must be able to monitor progress, evaluate performance against targets, and take appropriate actions to stay on track. This requires actionable information as well as management, analytic, and financial services.

To facilitate collaboration among physicians and other members of the care team and to coordinate the best care for patients, each physician needs timely access to relevant patient information, especially information about treatment from other providers. Typically, a patient sees multiple physicians, and his or her care is often not coordinated in a systematic way, which can result in redundant services, duplicative tests, adverse drug interactions, and in the worst-case scenario, adverse and irreversible patient events. Current interest in the "Patient-Centered Medical Home" concept reflects a return to when a single primary care physician or team was able to coordinate all aspects of the patient's care. Similarly, the ACO focus is on patient-centered care, in an era of more complex clinical management and greater concerns about quality and efficiency. In order to achieve greater integration and coordination within the delivery system, an ACO needs to serve as the information hub of its population, integrating data and keeping track of the care provided to patients by all its physicians, hospitals, and other providers as they work to improve the quality and efficiency of care. In doing so, an ACO can also generate the kind of meaningful performance information needed to provide better financial support for high-value, well-coordinated care.

Integrated delivery systems, such as Kaiser Permanente and Group Health Cooperative, have successfully incorporated their information technology (IT) with their care delivery systems to improve quality and efficiency; however, other physicians and hospitals that are less – or not at all – integrated can also improve quality and efficiency by creating virtual integration through the deployment of IT and comprehensive data management practices. In turn, these data capabilities can provide a foundation to pay more for better quality and lower costs, providing further support for care coordination.

In this section, we first provide an overview of the essential information and analytical resources needed to achieve a level of clinical integration that improves quality and reduces costs, and to create a "virtuous cycle" that enables further improvements. We then discuss the management, analytic, and financial services that an ACO must perform with the information it collects and analyzes in order to be successful. As there is an abundant array of data, tools, and services available today, we will provide examples of a few key elements, including:

- 1. Data exchange and data sources for it (4.1);
- Applications and tools that can provide physicians and their care teams with meaningful and useful information on a timely basis (4.2);
- 3. Reports for tracking financial and clinical performance (4.3); and,
- 4. The level and type of resources, tools, and services needed for a successful ACO (4.4).

4.1: DATA EXCHANGE

Creating a Data Exchange

Taken together, the full range of available data on services, tests, and prescriptions that have been provided to patients can provide a rich cache of facts and useful information about patients and physicians to achieve care improvements. These data can show how often and for what reason a patient seeks care and what care they have received. It can also show what services a physician has provided and which patient populations they serve. It can be helpful for both ACO providers and ACO management. For example, physicians should know if any of their patients with diabetes have gaps in care using evidence-based guidelines, and the ACO should know of all the patients with diabetes, the physicians responsible for these patients, and any gaps in their care.

Consequently, the ACO needs a capacity to integrate and store data on its patients and delivered services. To achieve this, the ACO should establish regular data feeds from its various data sources, integrate them, and form data links by unique combinations of patient and providers. We call this the "ACO data exchange."

There are many possible ways to start up a data exchange, with a number of software and service vendors that provide data exchange and analytic capabilities to health care organizations. In addition, off-the-shelf database programs are available at a low cost for beginning to build and support ACO data exchange. Historically, many organizations have set up static "data warehouses" to bring together the relevant information for supporting quality improvement and performance tracking. More recently, virtual data networks are emerging that use distributed data systems and are able to pull relevant patient data when needed. Many systems are effectively a combination, in which either real-time or periodic data feeds and/ or summary information from various data sources are enabled to support an organizational database. The key issue is the functional capabilities of the ACO data exchange; in general, exchanges that can produce more complete and timely patient-specific information to support patient care and summary information to track provider and ACO performance will enable more effective ACO implementation.

By collecting and integrating data on an ACO's patient population, the data exchange becomes the source of the various analytics necessary for both providing useful information to physicians to manage their patients' care, and for systematic quality and efficiency tracking and improvement. For example, a patient could generate a hundred or more records of medical claims, laboratory tests, and prescriptions annually, resulting in a large and complicated set of information. The data exchange would bring this large but important volume of patient-related data together and turn it into actionable information for ACO initiatives, either through using off-the-shelf software or purchasing data exchange services from a vendor for a monthly subscription fee. In either case, provided that data sources are available, the resulting integrated data exchange should not be expensive for the ACO, and would enable the ACO to perform a range of analysis, reporting, and tracking.

Sources and Timing of Data

With regular data feeds from the various sources that make up health care delivery, the ACO can develop data exchanges that enable both performance improvement and tracking. Of course, obtaining reliable and timely source information can be a challenge. ACOs can start with claims information. An ACO can use hospital and physician billing systems to track basic measures in clinical quality and costs of care. Procedure codes, revenue codes, diagnostic codes, and dates of service for identifiable patients are all valuable information to include in data gathering. Data can be provided directly from the billing systems or from the claims clearinghouses used by the ACO's physicians and hospitals. ACOs will also need to work with their payers to get claims data on care provided outside of their provider network.1 Physicians should be required to authorize data sources to release this information to the ACO as a condition for participation.

These data can and should be used retrospectively for evaluation purposes to determine if ACO performance criteria on quality and cost have been met. Data that show actual payments made by the payers (commercial payers and/or Medicare) can be used to compare the ACO's costs to its budget. However, to support providers in meeting and surpassing the benchmarks, evaluation reports that examine prior performance are not sufficient. Rather, timely, user-friendly reports must be given to the providers involved in care, with sufficient opportunity for them to act to close quality gaps. The evaluation reports are a secondary outcome for a data exchange primarily designed to support the ACO's activities to improve care. Using the same data exchange system for both supporting performance improvement and for ACO evaluation measures helps assure accuracy and validity of the performance measures, as well as alignment and provider support for the ACO's activities.

Providers should have data on their patients' utilization in as close to "real-time" as possible. This ensures that providers have all of the information needed to avoid unnecessary and potentially harmful care and helps them determine the most appropriate clinical course. However, claims data, particularly within the Medicare program, historically have not been provided on a timely enough basis to improve care. For example, the Government Accountability Office (GAO) reported a key shortcoming of the Medicare Physician Group Practice (PGP) demonstration program was Medicare's failure to provide paid claim information to the medical groups in a timely manner.² Instead, the physician groups had to use non-payer source data (like that described above) to support their data exchanges. More timely and consistent data from both public and private payers is a key priority for future ACO implementation.

Prescription data are also essential for verifying appropriate treatment, and are relatively easy to integrate electronically. In the event where prescription claims data is not available (such as Medicare Part D claims), a workaround may be developed. For example, the ACO could utilize e-prescribing and other electronic tools to track prescription fills to provide the same type of information. ACO exchange implementation should also begin the process of incorporating key clinical information. Physicians should authorize laboratories to release test results to the ACO, as laboratory test results provide another important electronic source of information for identifying gaps in care.

These data exchanges consisting of claims/billing data augmented with targeted, feasible clinical data provide a better foundation for tracking and reporting on meaningful ACO performance measures. For example, regular testing and collection of lab results both facilitates the appropriate management of chronic conditions, such as coronary artery disease and diabetes, as well as allows for the development of more meaningful health outcome measures that are not possible with administrative data alone. Rates of generic utilization and compliance with drug formularies can also be computed and provide evidence related to the efficiency of care.³

Electronic Health Records

Electronic Health Records (EHRs) are expected to become a much more important source of data for ACO activities, because it is an electronic version of a patient's medical history maintained by the provider over time.⁴ It may include all of the patient's clinical data under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports. The EHR automates access to information and has the potential to streamline the clinician's workflow. The EHR also has the ability to support other care-related activities directly or indirectly through various interfaces, including evidencebased decision support, quality management, and outcomes reporting. However, EHRs are currently limited in availability and completeness. Most small practices have not adopted them consistently, and those that have typically do not have information beyond their practice or practice site.

EHR implementation is likely to be gradual, with some capabilities and practices coming online before others. Interoperability (the ability to share data between EHRs in different medical practices) with other systems such as a disease registry is often not available today, as previous CCHIT certification did not require interoperability.⁵ As practically meaningful interoperability becomes more important in the future, data capture and sharing will become the rule and not the exception. Indeed, since siloed payments do not promote coordination across settings of care, ACO payment incentives based on patient-level performance measures that require interoperable exchange of data will add to the momentum for interoperability.

Consequently, planning for the incorporation of EHR data into an ACO data exchange will be an incremental process, but one where progress can be synergistic with the clinical transformation and payment reform goals of the ACO. For example, limited electronic record capabilities could initially be used to provide key clinical information and support for registries in the exchange, as described in the next section.

4.2: TOOLS FOR TIMELY COMMUNICATION WITH PHYSICIANS AND PATIENTS

Coordinating Care for Quality and Efficiency

From the start, the ACO needs to consider ways to communicate relevant information from its data exchange with providers and patients, particularly when changes are warranted to better meet the patients' needs. After all, such improvements in care are essential for the ACO's success. The ACO should adopt, whenever possible, valid evidencebased care guidelines, and use data exchanges to identify and intervene with physicians when the care provided falls outside of these guidelines. As an example, working with providers of care for lowerback pain, an ACO may establish a guideline that advocates physical therapy be tried before referring certain patients for a radiology imaging test or to an orthopedic surgeon. The guideline is designed to achieve both quality and efficiency goals. For Medicare patients, guidelines that help physicians determine the appropriate course of action may be especially important, as these patients often have several co-morbidities. Better coordination and communication among physicians will help clarify which conditions to treat first.

For these efforts to improve care delivery to succeed, the ACO needs to dedicate resources to assist physicians with appropriate patient care management. To do this, the ACO will need to use the data exchange to address six key areas:

- 1. The patients' treatment needs based on evidence-based guidelines;
- The physician's performance with respect to meeting the patients' needs;
- 3. The benchmarks for the cost of care;
- 4. The physician cost of care relative to these benchmarks;
- 5. The organization's effectiveness in improving quality; and
- 6. The organization's costs of care compared to its benchmarks and budget.

The Case for Disease Registries

Disease registries, without EHRs or with limited or more comprehensive EHRs, offer an effective, relatively inexpensive tool for identifying and addressing gaps in quality through an ACO data exchange. They can serve the dual purpose of providing timely information for care improvement, and the generation of performance measures for ACO payment contracts. Kaiser Permanente, the Group Health Cooperative, and other integratedcare organizations have achieved measurable quality improvements using disease registries, which identify whether the evidence-based needs of patients are being met, and track the physicians' and the organization's performance on quality measures. Advocate Health Care, the largest notfor-profit delivery system in metropolitan Chicago,

has successfully integrated data by instituting data registries to manage the care and track the performance of its primary care and specialist physicians. Advocate Physician Partners' Clinical Integration Program uses a registry that tracks 15 distinct diseases and preventive care populations, and assesses its performance on 110 clinical and efficiency measures.⁶ In the Medicare PGP demonstration project, all ten participants utilized a disease registry to track the patients with diabetes. Note that providers do not need to be associated with integrated delivery systems to use registries. Several states and other regional initiatives are supporting the development of health information exchanges that can support disease registries.

Employed in a wide range of care settings, disease registries today provide web-based options that allow physicians in various locations to access the same data. Full implementation of an EHR is not required, but it is necessary to have sufficient, timely administrative and clinical data exchanges to reliably identify meaningful opportunities for improving quality and cost. An EHR can provide the most up-to-date information on a patient, but it may be incomplete if it relies only on internal data or on systems that are not comprehensive. While potentially more limited in scope, an ACO disease registry combines limited internal and external data sources to address clear opportunities to improve care, by identifying patients with common needs - including specific diseases and/or qualifying for preventive care services - and providing timely information to help address unmet needs.

The data exchange should automatically populate the disease registries with data from physician billing, EHRs, medical claims, encounter data, hospitalization, laboratory test results, and pharmacy claims or e-prescribing to pinpoint any unmet needs, gaps in data, or gaps in service delivery. For example, a typical set of registry tools for a Medicare population should be able to identify and track populations with diabetes, acute and chronic cardiovascular diseases, heart failure, hypertension, osteoporosis, and end-stage renal disease. The set should also be able to track patients who are on persistent or high-risk medications.

For preventive care, registries should track colorectal cancer screening, breast cancer screening, and annual flu shots. While registries used to be maintained on paper, today's webbased, pre-populated registries derived from electronic data exchanges can provide physicians and other members of the care team with point of care and near-real time gap analysis to see if evidence-based services are missing or needed by their patients. Registries can also provide regularly updated feedback to physicians indicating the progress towards measurable goals of improvement in patient care.

The ACO, working with its payers and providers, will establish goals for quality improvement based on the historical data for its population and priorities. Capabilities to support the quality measures should be incorporated into the disease registry. For example, if care for patients with diabetes is an ACO focus, data on patients with diabetes should be captured as part of the registry, including valid measures such as use of diabetes screening tests and occurrence of preventable readmissions plus clinical results (such as hemoglobin A1c levels), if feasible. If flu shots are one of the measures, patients who should have annual flu shots should be an additional registry. Populating the registry with data on occurrence of flu shots - along with an opportunity to add data on shots not captured through administrative systems - then supports both improved clinical care and performance measurement. Organizations that have used registries for several years may be tracking patients in ten or more distinct registries. The registry tools available today are able to support registries for any distinct population that needs to be tracked by the ACO.

To illustrate how the disease registry process works, high-cost and high-risk patients – who need coordinated care the most – are identified in the data exchange either automatically from the claims data (through predictive modeling, for example) or by physicians adding these patients. If the ACO utilizes non-physician care coordinators in its care team, the coordinators then use the disease registry to track the care against the guidelines established Services are available to pre-populate disease registries using established data feeds and to organize the data so that physicians can readily utilize the registries to manage patient care. The registries may include a consolidated listing of patients with special needs, such as diabetes, cardiovascular disease, and asthma, as well as additional preventive care registries for screenings and immunizations.



EXHIBIT 4.1. CLINICAL DATA INTEGRATION ENABLES ALL THE PATIENT'S PHYSICIANS TO VIEW THE SAME INFORMATION

by the ACO and work with the physicians to address any gaps in care. Such capability provides the entire organization with the ability to view all the practice settings at once. For example, Exhibit 4.1 shows how viewing individual patient-level integrated clinical data can enable the physicians to coordinate, monitor, and provide the appropriate treatments for the patient.

Referrals

Physician referrals to another physician, hospital, or other service provider can also benefit from the timely communication and information sharing among providers afforded by an ACO data exchange and patient registries. Implementing evidence-based guidelines with the referred providers offers additional opportunities to improve care and avoid unnecessary costs. Decision support tools such as electronic reference databases can assist in identifying appropriate guidelines given patient histories.

The goal is not to restrict access to potentially beneficial services, but to give the providers and patients timely access to clinical information that can make the referral itself more effective (allowing better care coordination), and to help the ACO achieve a better understanding of the use of referral services for its patients. As mentioned in the earlier example, a physical therapy consultation is generally recommended as the first line of treatment for a new diagnosis of lower-back pain before ordering imaging studies or referring to a surgical specialist. This is different from a "utilization review" approach of questioning every referral in a purely volume-based payment system; in such cases, few requests are rejected for valid reasons, creating unnecessary administrative costs and burdens to physicians and heightening the lack of alignment and conflict between the providers and the available "support" systems. The use of more clinically sophisticated evidence-based guidelines based on meaningful data exchange can help promote best practices while keeping care decisions in the hands of ACO physicians.

4.3: TOOLS FOR TRACKING PERFORMANCE AND COSTS

Establishing and Tracking Budgets and Costs

The ACO, working with its participating payers, needs to set an annual medical cost benchmark based on its analysis of the organization's patients. The budget may be developed based on historical costs of the ACO's patients, adjusted for changes in risk factors and for trends in cost of care. Each month, the ACO can use its data exchange to sort, count, sum up, and compare data to the budget for monitoring and payment purposes. The comparisons would be performed based not just on overall benchmarks, but on benchmarks by payer and – depending on the ACO's planned activities – particular types of patients and services.

The cost of care has two components: cost per service, and frequency of the services provided. Opportunities for improvement can result from providing more low-cost services, such as monitoring a patient with heart failure with at-home care or physician's office visits so as to avoid a more expensive hospital admission. Thus, an ACO should have not only the baseline costs but also the baseline utilization rates of its various services, particularly key services that present opportunities for improving quality and efficiency. Part 3 of this toolkit provides additional information on ACO budget and financial performance.

Generating Reports to Assess Performance

To manage the information, the ACO should establish schedules for generating routine reports, including how frequently the reports should be produced, who should review the high level versus the detailed reports, and who can act on the information. Ad hoc reports can then be generated as needed to answer specific questions or to drill down on particular issues raised.

The sample reports in Appendix 4.A provide examples of the type of reports that could be generated from the ACO's data exchange. They include reports that track an organization's costs and utilization on a high and detailed level, and reports that track an organization's quality performance, with examples of the information included in the disease registries. As more sophisticated person-level measures become available through increasingly detailed registries and EHR capabilities, the data exchange will be able to provide more sophisticated support for performance monitoring and improvement.

Analytical Tools and Reporting for Case-Mix and Risk Adjustments

In addition to data exchanges and disease registries, there are many other tools that an ACO can utilize for analytics and reporting, and can potentially augment the information given to providers to support improvements in care.

The above tools are available as licensed software applications or as services provided by vendors that have built their own reports using these applications. These tools can be used for casemix or risk adjustment. Performance measurement of an ACO or its providers is impacted by the underlying risk and severity of the patients they manage. Case-mix or risk adjustment addresses these differences and supports more consistent and equitable comparisons.

See Appendix 4.A for additional information on tools and methodologies for risk adjustment, tracking episodes-of-care, and quality measurement.

4.4: ASSESSING THE APPROPRIATE LEVEL OF RESOURCES, TOOLS, AND SERVICES NEEDED FOR AN ACO

Developing a Budget

To achieve improved clinical performance and the integration to support it as an ACO, each organization has its own set of needs and budget constraints. As a first step, an ACO should develop a budget for the information, tools, and expertise it needs to implement a data exchange and support the use of the data for improving care and tracking ACO performance. The budget would vary depending on the size of the organization, the current level of integration, the level of integration it plans to achieve in order to improve care, the required resources to achieve its goals, and the options that offer the most appropriate level of technology sophistication. For example, an ACO with a small patient population should set more modest goals to align resources invested with what the ACO could ultimately earn in incentive payments.

Budget development should consider multiple federal sources of funding that can support these ACO information capabilities. First, the American Recovery and Reinvestment Act (ARRA) of 2009 included "meaningful use" incentives in Medicare and Medicaid for physicians and hospitals to adopt EHR systems. Under the meaningful use program, physicians can receive up to \$44,000 if they can demonstrate that they have adopted and meaningfully used EHRs. Initial requirements are tied to limited data exchange and tracking capabilities very similar to those described here, and the U.S. Department of Health and Human Services has emphasized that more advanced requirements in later years will be tied to demonstrated impacts on clinical quality and outcomes of care that also appear very consistent with ACO performance measures. Second, as part of its voluntary Physician Quality Reporting Initiative (PQRI), CMS has established a mechanism for submitting quality information via electronic registries, which if designed properly can be very consistent with the ACO patient registries described above. It is likely that further payment reform pilots to be announced by CMS will also focus on these kinds of data exchanges for care coordination and meaningful performance measurement.

Performing Information "Gap" Analysis

The next step is to assess the gap between the organization's current capability, where it needs to be, and the specific tools and resources required to fill the gaps. The key is to identify the information that is missing or needs enhancement, and equally important, to clarify the purpose of that information. Organizations that have been successful in

achieving quality and efficiency improvement have found ways to organize health care data to provide robust, valuable information.

In performing the information gap analysis, a few key questions an ACO may address include the following:

- 1. Is the information sufficiently accurate, complete, reliable, consistent and robust?
- 2. How will the information be used? What are the objectives of using this information? Will it be used for facilitating timely communication to improve care, for quality benchmarking, and/or for financial planning and monitoring?
- 3. How timely does the information need to be?
- 4. Is the information meaningful and actionable, and if not, what additional data are required to make it so?
- 5. What kind of systems does the ACO need to create and maintain the data exchange to produce this information?

After an ACO has identified the areas that will need additional tools and resources, it will need to develop a plan to work with vendors or consultants to implement the information systems required to develop its data into workable formats and analyze it to support ACO activities.

ACO Administrative Services Requirements

ACOs will need to handle a variety of management, analytic, and financial services. Many provider groups forming an ACO will need to start accepting and managing risk for the first time, at least for bonuses based on shared savings. Managing this accountability, partly through improved information on costs and quality, is an important reason for ACOs to have access to certain key services – especially since the shared savings are derived by comparing per capita spending on all services (across all providers within an ACO) to the per capita budget targets. Many of these services can be provided internally by staff of the ACO. For example, financial reporting is a standard requirement for most health care providers today and will not be substantially different for an ACO. Other services, however, may be harder to provide with internal resources, especially those related to insurance-like functions, such as timely access to claims adjudication, utilization management, or distributing bonus payments associated with shared savings.

ACOs will have differing levels of capabilities, with some needing to provide more new services than others. Several services will be particularly important for an ACO to provide or obtain, including:

1. Claims Adjudication

ACOs will need timely claims data for services from both ACO and non-ACO providers, which will need to be adjudicated for payment by an organization with claims payment skills. Depending on the contracted payment methods, claims payment may be straightforward if they are based on common rules or complicated if they involve new payment methods such as bundled payments. Regardless of how actual payments are resolved, the claims data are necessary for both tracking performance and identifying specific areas for improvement.

For Medicare, claims could be processed by a Medicare Administrative Contractor (MAC) or other data contractor, or the ACO might process its own claims. Timely access to such claims has been a technical challenge in the past, but efforts are underway at CMS and its contractors to provide data much more quickly.

2. Network Contracting

To the extent that the ACO chooses not to use either fee-for-service (FFS) Medicare pricing for Medicare patients or private payer contracts for non-Medicare patients and instead establishes its own payment terms for member or contracted providers (to whom referrals may be focused), it may need to obtain access to the necessary discounts on its own. Although this can be done through preferred provider organization (PPO) network rentals for a fee, PPO network rental contracts may not be as favorable as either that of Medicare or private payers with dominant market shares. As an alternative, the ACO could negotiate its own standard contracts with its member providers and other participating providers; for example, at 100 percent of Medicare for Medicare beneficiaries and 115 percent for commercial members.

3. Bonus Settlement Adjudication (After the Claims are Paid)

Another type of ACO financial transaction is the payout of any accrued bonuses. There are two bonus settlement adjudications. The first is the aggregate bonus pool, which involves three determinations: the actual performance against a target, interim determinations of financial and quality performance (in advance of having complete, fullyear data), and deciding when to allocate funds. The second settlement adjudication involves how the ACO will allocate the bonus funds among providers. Approaches to allocating the bonus funds across providers participating in the ACO can range from being relatively simple to guite complex. Before the start of the year, an ACO must specify the rules under which the bonus amounts are to be distributed and implement a financial mechanism for retaining and then distributing such bonuses.

ACOs will need to ensure that the right capabilities are available either in-house or through a vendor to provide the necessary reporting and analytical tools needed to determine the allocations. Also, a process for handling bonus disputes may need to be developed.

4. Physicians Organization Management Services

Depending on the structure of the ACO, it may need to manage emerging physician practices or other integrated delivery systems. While hospitals typically have well-developed management structures (e.g., finance, IT, contracting and quality improvement), many small physician practices may not have these capabilities. They may want to develop these capabilities in-house or obtain these services from external organizations on a fee basis. Presently, many physicians outsource their billing and collection functions. Physicians should be encouraged to change their referral patterns to be based on efficiency, appropriateness of care, and quality metrics, and to refer patients to participating ACO providers.

5. Care Coordination and Utilization Management Services

Care coordination is a very important function for an ACO. The greater the effectiveness of care coordination, the more likely an ACO is to meet or exceed its budget savings targets. "On the ground" care coordination will likely be accomplished in the physician office, but assistance may be needed with other work related to registries, post-discharge coordination, disease management reminder calls, and other similar activities. Hospital partners may be able to supply assistance. New health IT software may provide further help. However, some practices may want to combine their efforts with support from vendors. An ACO may want to invest in acquiring the care coordination and utilization management services, which can either be "owned" by the ACO or subcontracted to other vendors. For example, specialty benefit management companies that provide criteria and utilization management services for high cost services, such as advanced imaging, may be one of the services to subcontract to an outside vendor.

Possible Sources of Service

While some fully integrated delivery systems will already have the capabilities to perform the above services, the majority of organizations will need to develop or purchase these capabilities. A critical decision for many organizations will be whether to develop the capability in-house, to outsource, or use a combination of the two.

Many health care organizations believe that they must invent their own tools and solutions internally. However, outsourcing has its benefits. The most notable benefit is that a company whose services and products are its core competency can offer the products and services more cost-effectively and efficiently than by doing them in-house. Learning from others not only allows the organization to take advantage of the best practices and the proven ideas, but it could also help avoid costly mistakes.

To determine how it can use data systems to achieve improvements in quality and cost, the ACO must initially focus on understanding its needs, planning for these needs in terms of resources, and then carefully evaluating available options. It may provide a competitive edge for the organization to focus initially on adopting the tools and resources that would enable the organization to show positive outcomes early in the process. Multiple resources and tools are available to assist in the development of the ACO, along with the experience and lessons learned of organizations that have managed the transition successfully.

Below are several possible sources of services that can help enable an ACO to function successfully:

Private Payer Services

Private payers will be able to provide a variety of services. If the ACO is in a synergistic contract with a major private payer, it is likely to want to make use of many of the services that the private payer offers. The services include:

- Access to the payer data to identify and attribute beneficiaries;
- Possible use of payer contract rates with ACO participating providers;
- Use of payer contract rates with providers "outside" the ACO;
- Claims adjudication;
- Data analysis services performed by the payers' actuarial or analytical staff;
- Use of certain utilization management services such as the nurse help-line or contracts with Radiology Benefit Managers (RBM); and
- Calculation of bonus amounts according to agreed-upon formulas.

For some activities, particularly utilization management and care coordination services, an ACO and its management team may prefer to handle in-house. However, it may be more efficient to obtain other services externally through payers or vendors, where the infrastructure is already in place and can be operated at marginal cost rates, such as a nurse help line.

Centers for Medicare & Medicaid Services

CMS obtains many administrative services at relatively low per-unit cost rates, and those services are obviously relevant to ACOs providing care for Medicare beneficiaries. In particular, CMS contracts with MACs to adjudicate claims using Medicare payment rules. If an ACO is going to pay all or some of the claims for Medicare beneficiaries at FFS Medicare rates, it would get the most favorable payment rates by going through these existing arrangements. This assumes that the Medicare-ACO rules would permit access to these services. One option would be for the MACs to adjudicate the ACO claims as they do for the FFS members, and in addition (or through another Medicare data contractor) provide regular, detailed, and timely electronic reports on utilization of services by beneficiaries in the ACO.

At the same time, the ACO should be vigilant in the areas of fraud and abuse and in terms of opportunities to address unnecessary utilization. While CMS and its MACs have taken many steps to control fraud and abuse, there are many instances where problems have been found.

CMS may also be able to provide some basic data services to the ACOs; however, CMS staff is already burdened with many activities. Other than determining shared savings and processing and reviewing claims payments, the extent of assistance that CMS staff or its contractors will be able to provide is not yet clear.

Services from Large Multi-Specialty Provider Groups, Management Service Organizations (MSOs), or Other Similiar Organizations

Certain integrated delivery systems, such as Intermountain Healthcare, have long and successful histories as health systems. Large, multi-specialty

EXAMPLES OF MSO SERVICE OFFERINGS

Based on the websites of several MSO firms, the following types of services are available in today's capitated medical group environment. These services are the same as or very similar to those needed by ACOs. They may include:

- Efficient method for claims and encounter submission, processed electronically or manually.
- Authorization workflow that provides timely application, processing, storage and emailing back to medical group providers.
- Web-based electronic medical management systems to connect with electronic medical records or through fax-based data entry.
- Compliance reports that allow providers and medical directors to measure their compliance rates and compare them to those of their peers.
- Provider tools and training to continuously educate providers and their staff.
- Referral management, such as using the website and submitting requests online. Systems allow providers to track the status of requests at any time and minimize unnecessary phone time for provider staff.
- Referral tracking reports available to send to each primary care physician (PCPs) on a monthly basis. This report allows the PCPs to ensure all members will obtain the services that they need. A similar report of members with critical conditions is available for the appropriate specialists to ensure that they make arrangements to see the members quickly.
- Customized financial reports tailored to a medical group's needs, including profitability by contract or by physician, monthly reporting packages, and monthly analytical reports.
- Risk pool reports that can be designed to monitor and analyze pool performance, and pro forma forecasting tools to assist the medical group as needed (e.g., to monitor ACO budgets).
- Member education programs and special classes for members.
- Patient handbooks and newsletters.
- Contract Management, including:
 - Health plan contracting and negotiations
 - IPA/Physician contracting and negotiations
 - Hospital contracting and negotiations
- Credentialing functions for every contracted IPA provider, including hospital-based physicians.
- Developing and maintaining comprehensive Quality Improvement Programs that continually evaluate, monitor, and identify areas to improve the quality of clinical care provided to members and the provider panel.

groups, such as Geisinger in Pennsylvania and Hill Physicians in California, have also successfully met their own service needs over the last 20 years. It is possible that negotiating for services with these provider organizations - or related organizations such as MSOs and actuarial consulting firms may be beneficial, as these organizations already perform services that are closely tailored to the needs of ACOs. For example, some of these groups have been paying claims and calculating bonuses that are shared among provider partners. Many have experience in the quality measurement metrics, such as the California provider groups that received incentive payments under the Pay for Performance program led by the Integrated Healthcare Association.

Another service that may be contracted is management consulting support to help with the set-up and ongoing management of complex provider organizations. ACOs may be able to draw on the lessons learned by already successful groups, rather than re-inventing the wheel.

Other Third Party Vendors

There are independent vendors, unrelated to private payers that are able to provide some of these services. Various kinds of utilization management services are readily available, such as services that provide hospitalists for hospital management, nurse hotlines, RBMs, and other similar therapy-specific managers.

In addition to clinical management services and claims adjudication, there are many actuarial/ financial consulting firms and a few data analysis firms available to provide the necessary services. Some of the data analysis firms on the West Coast have provided analytical services to large multispecialty groups and PHOs for over a decade. While ACOs are different from the capitated provider groups, there are many similarities between the two groups, so vendors could transition to the ACO services quickly.

Possible Timeline for Setting Up ACO Services

Organizations interested in forming an ACO need to build in sufficient time to put in place the necessary support infrastructure and processes. Each organization will require different lead time, depending on its own circumstances. Exhibit 4.2 provides a sample timeline for setting up the ACO services. One way for an ACO to set up its operations quickly is to initially rely on leased services provided by existing MSOs or other similar organizations with a proven track record.

This timeline assumes:

- An MSO would be engaged to provide some of the services;
- Other ACO start-up processes (e.g., establishing the panel of ACO physicians, arranging contracts with payers, etc.) would proceed on parallel tracks;
- All tasks are accomplished without significant delays; and
- The managers are dedicated to the decisionmaking process with sufficient staff support.

EXHIBIT 4.2. SAMPLE TIMELINE FOR SETTING UP ACO SERVICES

This timeline assumes a start date of 1/1. The schedule of setting up the necessary activities, from the time a decision is made to form an ACO to the ACO operation start date, is shown below:

1/1	Decision to form an ACO is final and an implementation work group is assigned.
2/1	Inventory of the ACO service capability (e.g., utilization review, claims adjudication, etc.) is completed.
3/1	Discussion among ACO managers, physicians, and staff regarding the services to be provided internally and the services to be leased.
4/15	Final decision by the ACO on the type of services that are needed.
5/1	RFP to be prepared by the ACO managers/consultant.
6/15	RFP released by the ACO managers to MSO vendor candidates.
8/15	All MSO vendor proposals received.
8/15-31	MSO services reviewed and clarification requested.
9/15-9/30	Final MSO terms negotiated by ACO managers.
10/1	Final decision of MSO vendor(s) decided by ACO managers.
10/1-12/31	Implementation preparation.
1/1	ACO operation start date.

CONCLUSION

Successfully managing an ACO requires not only capturing significant amounts of new data, but also effectively transforming that data into actionable performance measures that can offer providers timely feedback on the costs and quality of care. Building a robust data exchange is part of the solution to bringing together the various sources necessary to collect and process this data. Equally, ACOs must invest in developing a number of new processes to ensure both timely reporting and decision-making based on this incoming data.

Developing these support processes, even with the use of outsourced providers or other external parties will take time. A provider need not have the "perfect EHR" to begin undergoing this transformation. Nor should providers misconstrue these needs as a prescription for structural integration. In fact, much of the monitoring and reporting described here can be done by introducing new data elements from providers' existing billing systems, intermediaries, and plans.

It should be expected that over time, ACOs would work towards enhancing their infrastructure. As the information exchange and other service capabilities advance, ACOs will be able to support more advanced levels of performance measurement and payment models (see Part III for a discussion of the potential evolution of performance measurement and payment models under the ACO framework). In fact, all of these activities – setting performance goals, developing supporting payment models, and building the infrastructure for higher quality care - should be expected to occur in coordination with the organization's larger development plan for coordinating care. In this sense, identifying gaps in capabilities will need to be a continuous process as health care priorities evolve and infrastructure improvements allow for greater opportunities for improving system effectiveness and efficiency. In Part 5, we provide specific examples of how these enhanced support services can translate into improved clinical performance.

APPENDIX 4.A

Reports to Track Costs and Utilization

Figure 4.1 provides a high level overview of the ACO claim costs by provider specialty. The report compares the per member per month (PMPM) incurred claims in the current 12-month period with those incurred in the prior period, as well as with the target claim costs. For example, under the PCP Internal Medicine specialty, the current period claims PMPM was \$4.81, compared to \$4.46 PMPM in the prior period and the target of \$4.73 PMPM.

The provider specialty can be categorized into: allergy & immunology, anesthesiology, cardiology, dermatology, emergency medicine, endocrinology, gastroenterology, hematology/oncology, hospital, infectious disease, internal medicine, laboratory/ pathology, mental health, neonatal, nephrology/ dialysis, neurology, obstetrics/gynecology, ophthalmology/optometry, PCP-family practice, PCP-internal medicine, PCP-pediatrics, PCP-urgent care, and other.

Figure 4.1: Organization Cost Compared to Budget

Summary Cost by I	Provider Specialty						
ACO							
October 1, 2008 thro	ough September 30, 20	09					
IBNR used for curre	nt "Claims" only: 1.02						
"PRIOR" indicates: Jan 08 to Dec 08 - Prior Member Months: 308,992							
"CURRENT" indicates Oct 08 to Sep 09 - Current Member Months: 265,164							
Provider Specialty	Prior Total PMPM Incurred Claims Current Total PMPM Incurred Claims Comparable						
Hospital	\$6.36	\$6.60	\$3.48				
Laboratory/ Pathology	\$2.38	\$3.37	\$6.55				
PCP: Family/ General Practice	\$9.08	\$9.88	\$5.93				
PCP: Internal Medicine	\$4.46	\$4.81	\$4.73				

Figure 4.2 shows the cost and utilization trends for four reporting periods – prior three calendar years and the latest 12 months (LTM) yearover the prior periods. For example, in the current period, the number of procedures performed was 580,164; the total overall claim cost was \$35.66. The current period over the prior period trend for the pmpm claims costs, annual utilization, and cost per procedure were 7 to-date. It shows the PMPM claim cost, annual utilization per 1000 lives, the average cost per procedure, and the corresponding trends was \$20,691,324; the PMPM claim cost was \$78.03; annual utilization per 1000 lives was 26,255; and the average cost per procedure percent, 27 percent, and -16 percent, respectively.

FIGURE 4.2: COST AND UTILIZATION TRENDS – TOTAL

Drill Down Cost & Utilization								
ACO								
Cost & Utilization Study	Pe	riod 1	Ре	riod 2	Pe	riod 3	Pe	riod 4
by Intelligent Healthcare	Jan 01, 06	3 - Dec 31, 06	Jan 01, 07	⁷ - Dec 31, 07	Jan 01, 08	s - Dec 31, 08	Oct 01, 08	: - Sep 30, 09
Jan 01, 06 through Sep 30, 09	IBNF	:: 1.0000	IBNF	:: 1.0000	IBNR	:: 1.0000	IBNB	: 1.0160
	Membe	er Months:	Membe	er Months:	Membe	er Months:	Membe	er Months:
	30	3,668	33	4,380	29	7,360	26	5,164
Specialty & Procedure Code	Pe	riod 1	Ре	riod 2	Ре	riod 3	Pe	riod 4
Groupings	Procedur	es & Claim \$	Procedur	es & Claim \$	Procedur	es & Claim \$	Procedur	es & Claim \$
Grand Total	648,496	\$29,617,865	644,084	\$26,562,294	512,716	\$21,696,165	580,164	\$20,691,324
PMPM with percent change	\$75.24		\$79.44	6%	\$72.96	-8%	\$78.03	2%
Annual Utilization with percent change	19,768		23,114	17%	20,691	-10%	26,255	27%
Per Unit Cost with percent change	\$45.67		\$41.24	-10%	\$42.32	3%	\$35.66	-16%

Figure 4.3 shows an example of the next level drill down view of the cost and utilization trend, by provider specialty. The format is the same as the report in Figure 4.2. In this example, for the cardiology group in the current period, the number of procedures performed was 8,236; the total overall claim cost was \$653,518; the PMPM claim cost was \$2.46; annual utilization per 1000 lives was 373; and the average cost procedure were 11 percent, 9 percent, and 2 percent, respectively. Further drill down by procedure code groupings within the specialty is available (not shown here). Usually reviewing drill downs helps pinpoint areas that generate anomalies or require further investigations. The current period over the prior period trends for the PMPM claims costs, annual utilization, and cost per per procedure was \$79.35.

FIGURE 4.3: COST AND UTILIZATION TRENDS – SPECIALTY LEVEL

Drill Down Cost & Utilization – Specialty Level								
ACO								
Cost & Utilization Study	Per	iod 1	Peri	od 2	Peri	od 3	Peri	od 4
by Intelligent Healthcare	Jan 01,	06 - Dec	Jan 01,	07 - Dec	Jan 01, (08 - Dec	Oct 01,	08 - Sep
Jan 01, 06 through Sep 30, 09	31	, 06	31,	07	31,	08	30	60
	IBNR:	1.0000	IBNR:	1.0000	IBNR:	1.0000	IBNR:	1.0160
	Member	Months:	Member	Months:	Member	Months:	Member	Months:
	393	,668	334	,380	297	,360	265	,164
	Per	iod 1	Peri	od 2	Peri	od 3	Peri	od 4
Specialty & Procedure Code Groupings	Proce	dures &	Proced	dures &	Proced	dures &	Proced	lures &
	Cla	im \$	Clai	m \$	Clai	m \$	Cla	ш \$
PROVIDER SPECIALTY: Cardiology	10,112	843,521	9536	752,831	8,496	660,665	8,236	653,518
PMPM with percent change	\$2.14		\$2.25	5%	\$2.22	-1%	\$2.46	11%
Annual Utilization with percent change	308		342	11%	343	%0	373	%6
Per Unit Cost with percent change	\$83.42		\$78.95	-5%	\$77.76	-2%	\$79.35	2%

Reports to Track Costs and Utilization

Figure 4.4 shows the frequency and cost of all the high-cost cases by diagnosis codes in the current period. This report enables the ACO to identify the individual high-cost patients who require extra care coordination. This sample report includes the costs associated with the professional services, and excludes the hospital

FIGURE 4.4: HIGH-COST CASES BY DIAGNOSIS

costs. Patient-detail information is available for further drill down. In total, there were 273 high cost patients incurring 175,249 procedures, with \$4,095,043 incurred claims and an average cost of \$15,000 per patient. In conjunction with the total claims reported in Figure 4.2, it showed 20 percent (\$4,095,043/\$20,691,324) of the overall costs was attributed to a relatively small number of high-cost cases.

High Cost Cases B ACO	y Diagnosis					
October 1, 2008 thro	ough September 30	, 2009				
Member Months:	265,164					
IBNR: 1.016						
Diagnosis Code Group	Annual Frequency	Outlier	Procedures	Claims	Claims	Claim Cost
	Per 1,000	Cases			PMPM	Per Case
Injuries, Sprains, Strains, and Poisoning	0.6	13	1,987	145,491	\$0.56	11,192
Nephritis, Nephrotic Syndrome, Nephrosis	0.5	11	71,631	349,896	\$1.34	31,809
Diseases of the Respiratory System	0.2	5	835	55,362	\$0.21	11,072
Congenital Anomalies	0.1	2	382	41,862	\$0.16	20,932
Grand Total	12.4	273	175,249	4,095,043	\$15.69	15,000
physicians within the same primary care specialty - can then be further evaluated. The specialty and ancillary providers can be categorized Figure 4.5 shows the referral costs to specialty and ancillary providers by PCPs. The outliers – the PCPs with high utilization rates among gynecology, ophthalmology, physical therapy, radiology, surgery, and all other. This report can be further enhanced by incorporating caseinto: cardiology, dermatology, emergency medicine, hospital, internal medicine, laboratory/ pathology, mental health, obstetrics/ mix and risk adjustment methodology to provide a more equitable comparison.

FIGURE 4.5: REFERRAL COSTS AND REFERRAL RATES

Referred Service Costs (***exclude:	s hosp, lab, OB	/GYN & PCP)						
Medical Group								
October 1, 2008 through September (30, 2009							
Member Months: 265,164								
Ranking Key								
^^ indicates greater than the mean +2	2 standard devia	ttions						
A indicates greater than +1 standard	deviation over tl	he mean						
PCP Specialty and Name [excludes PCPs with less than 1,000 mbr mo]	Assigned Members	PCP self	Cardio	Hosp	Lab	All Other	Total PMPM***	Rank
PCP: family/gen practice				er member l	Per month			
MD, Elizabeth	9,198	\$17.05	\$4.50	\$5.72	\$8.76	\$5.05	\$52.72	<
MD, Alan	7,750	\$14.11	\$4.52	\$5.11	\$8.29	\$6.93	\$59.04	< <
MD, James	6,230	\$20.83	\$8.31	\$8.13	\$11.14	\$3.60	\$62.50	~~
MD. Michael	8,707	\$17.34	\$4.42	\$4.69	\$7.24	\$5.45	\$47.49	<

Figure 4.6 is a quality scorecard by physician. It shows a sample of the physician's year-to-date scores indicating his/her clinical and efficiency performance.

with drill down that shows the patients who do not meet the clinical effectiveness requirements. One report may show the cardiovascular The patients' registries are available in different formats. One report may show the year-to-date scores on each of the quality measures, patients with high LDL cholesterol value. Another report may show the key statistics of an individual patient with diabetes, such as the clinical observations, blood pressure, dates of laboratory visits/eye exams, and current medications.

FIGURE 4.6: QUALITY SCORECARD

Clinical Integration "Quality" Report Card				
2009 Clinical Integration Progress Report – INDIVIDUAL REPORT				
4th Quarter Registry Data Collected through November 30, 2009				
Family Medicine				
Clinical Integration Requirements	Denominator	Numerator	Results	Points
Medical and Technological Infrastructure				
Use of Registries				
CIRRIS Initiative Reporting Compliance (>= 75%)				1.00 of 1.00
CIRRIS Physician/Office Access (>= 4)			170	1.00 of 1.00
Clinical Effectiveness				
Smoking Cessation Counseling				
Outpatient- Children Pediatric Second Hand Assessment (>= 50%)			No Eligible Patients	0.00 of 0.00
Outpatient- Children Pediatric Second Hand Counseling (>= 50%)			No Eligible Patients	0.00 of 0.00
Outpatient- Registry Smoking Patients Counseled (= 100%)			No Eligible Patients	0.00 of 0.00
Coronary Artery Disease				
% of Blood Pressure Measurement (<= 90%)	ю	ю	100%	0.20 of 0.20
% of LDLs < 100 mg/dL (>= 56%)	ю	ю	100%	0.10 of 0.10
Body Mass Index (>= 50%)	С	ი	100%	0.10 of 0.10
Diabetes Care				
% HbA 1c performed (>= 81%)	44	33	75%	0.00 of 0.50
% LDL performed (>= 79%)	44	36	82%	0.50 of 0.50
Nephropathy Testing (>= 60%)	44	37	84%	0.50 of 0.50

ENDNOTES

1. Claims intermediaries could potentially bypass the need to get data indirectly through a plan. Currently, the standard way to assure complete data, at least on utilization, is to get data from the payer. However, since intermediaries (i.e., billing systems) are able to directly report this data to providers on much shorter timeframe through the exchange model bypasses, thus bypassing payers and reducing the delivery time for data.

2. GAO, Report GAO-08-65 at www.gao.gov/new.items/d0865.pdf

3. For more detail on the types of measures data exchanges should support: McClellan, et al. "A National Strategy to put Accountable Care into Practice." Health Affairs. May 2010.

4. CMS, Electronic Health Records overview, see www.cms.hhs.gov/ehealthrecords

5. Certification Commission for Health Information Technology, see http://www.cchit.org/

6. For a copy of Advocate's Clinical Integration Program annual report, see http://www.advocatehealth.com/documents/ app/value%20report.pdf. For more information: Mark C. Shields, Pankaj H. Patel, Martin Manning and Lee Sacks. A Model for Integrating Independent Physicians Into Accountable Care Organizations. *Health Affairs*, no. (2010): doi:

10.1377/hlthaff.2010.0824

Part 5

Health Care Delivery Transformations for Achieving High-Value Health Care

Mark McClellan, Andrew Kruegar, Sue Podbielski



ACCOUNTABLE CARE ORGANIZATION

PART 5: HEALTH CARE DELIVERY TRANSFORMATIONS FOR ACHIEVING HIGH-VALUE HEALTH CARE

By definition, ACOs are held accountable to achieve high levels of patient outcomes and satisfaction, at lower health care costs. As part of this mission, delivery transformations should seek to achieve three aims, consistent with all recommendations in this toolkit:

- **Provider infrastructure** to coordinate and improve care, including:
 - Organized provider activities (e.g., a strong primary care provider foundation, and leadership to effectively involve key types of providers in performance improvement activities);
 - Timely data reporting and analysis; and
 - Health IT to facilitate the sharing of information across providers in an efficient manner.

The ability to coordinate care allows ACOs to influence the health and health care of the patient population for whom they are accountable. An ACO is accountable for the overall quality and cost of care for its attributed patient population. Responsibility extends not just to the services provided or conditions treated by providers affiliated with the ACO, but to all care received by patients assigned to the ACO. As a result, ACOs benefit from the ability to manage and coordinate care of their patients across the full spectrum of services delivered to their patients.

• **Performance Measurement** to evaluate the impact on patients' care experience and quality of outcomes on their total health. Key goals of performance measurement are to ensure accountability for the quality of care and to identify and drive improvement in areas of substandard care. For example, performance measurement can identify the potential savings

and quality improvement for an ACO's patient population with low levels of both generic prescription drug utilization and medication adherence, as indicated by measures of generic prescribing and refill compliance or frequency.

Shared Savings as a funding source for many delivery reform efforts that are often not directly reimbursable under fee-for-service (FFS) and other traditional payment systems. For example, shared savings could be used to help sustain improvements in health IT that may allow the better coordination and communication of care across providers. ACOs should consider investigating both the shortterm and long-term opportunities to qualify for shared savings. In the short term, ACOs should aim for interventions that can guickly generate savings and return on investment - such as interventions designed to reduce hospital readmissions or relatively simple interventions that correct clearly identified inefficiencies in care delivery. ACOs should also consider ways to build on these investments for longer term savings - such as further steps to improve chronic disease management through the availability of more sophisticated, timely information and delivery reforms.

Reforming the delivery of care to improve health results for patients while lowering overall costs is both difficult to accomplish and essential for the success of an ACO. In 2009, the Bipartisan Policy Center (BPC) released a report identifying interventions and reforms with the greatest potential to make a meaningful impact on the quality and value of health care. Specifically, they cited a number of promising approaches that may lead to long-term savings, including: targeting interventions to specific patient populations or clinical areas; introducing real accountability from providers and patients; transitioning provider reimbursement away from volume and towards value; and integrating multiple delivery system reforms together.¹ In this section, we describe a range of strategies, including many noted by the Bipartisan Policy Center, that have been implemented in both the public and private sector to achieve these core ACO objectives. The evidence on most of the strategies discussed in this section is mixed, and the best opportunities for a particular ACO are likely to depend on the circumstances, ideas, and leadership of its providers. To achieve success, clinical reform initiatives should be part of an overall strategy that can feasibly lead to a significant impact on costs and meaningful performance measures in accordance to the aims described above. Moreover, it is important for ACOs to implement these transformative strategies flexibly and with willingness to experiment with a variety of approaches.

The types of delivery reforms that ACOs should consider fall into four dimensions:

- Care coordination (5.1);
- Population or condition specific treatments (5.2);
- Patient engagement in care (5.3); and,
- Infrastructure and organizational redesign (5.4).

5.1: CARE COORDINATION

The current health care system is fragmented, which can lead to preventable and/or high-cost medical care. To start addressing this fragmentation, ACOs should first consider interventions that target high-cost delivery processes where coordination problems lead to identifiable and measurable opportunities to reduce complications and costs. These types of interventions may include: addressing avoidable hospitalizations and readmissions through better care transitions and case management for patients with complex illness; more effective care coordination within care settings; and other structural and process interventions that can encourage greater collaboration and teamwork between health care providers. One study found that approximately

14 percent of elderly patients transitioning from the hospital to the home experience medication discrepancies, which more than doubles their chances of readmission.²

Better care coordination and care management can also help to ensure that patients receive care in the most appropriate, least intensive setting as possible, and that care is not duplicated or conflicting. Given that the average Medicare beneficiary visits two primary care providers and five specialists annually, this presents a key opportunity for savings.³

Care coordination can refer to a number of strategies that aim to emphasize overall responsibility for the entire care process and provide additional resources to providers to promote preventive care, improve care transitions, and encourage information exchange as patients transition from one care setting to another. Established systems and processes that encourage joint decision making can help support timely, multi-directional communication within and across provider practices. These activities are particularly valuable for Medicare patients with multiple chronic conditions who are at high risk for costly complications. Typically, these activities are not reimbursed reasonably, if at all, in FFS payment systems.

Below we highlight several promising examples of strategies that can improve care coordination.

Care Transitions

Without planning and careful monitoring, postdischarge patients – in particular older patients with multiple chronic conditions – are at greater risk for readmissions and avoidable complications that can drive up health care costs. To address this concern, providers and researchers have developed a number of interventions aimed at improving followup care and communication across providers. For example, providers in a large integrated delivery system located in Colorado have developed a care transition program that targets elderly patients to improve care transitions from the hospital to the home. Specifically, the program includes two key components: (1) the development of a personal health record owned and maintained by the patient to facilitate cross-site information sharing, and (2) a series of visits and telephone calls with a transitions coach trained in medication review and reconciliation. These two components are designed to encourage patients and their caregivers to take a more active role in care transitions and foster more effective care coordination. In randomized control trials, the intervention resulted in up to a 28 percent reduction in hospital readmissions for up to six months after the original hospitalization.⁴

Another method proven to help successfully coordinate and streamline transitions is the Transitional Care Model (TCM). TCM is designed to address transitions across physical settings and in health status for older Americans with complex needs by having an advanced practice nurse lead patients through transitions using an evidencebased care plan to coordinate their care. This includes a comprehensive assessment of patient and caregiver needs and focuses on increasing patients' and caregivers' ability to self-manage their care. The nurses in the TCM each manage an active caseload of approximately 15 to 20 patients, helping ensure each patient gets the attention they need during one of the most vulnerable parts of the care process.

The TCM has been shown to consistently reduce the time to first readmission, total number of readmissions, and inpatient days, resulting in significant decreases in health care costs. A recent study found that over 52 weeks post-discharge participating patients experienced 36 percent fewer readmissions with an estimated mean per-patient savings of approximately \$5,000.⁵ Patients, family caregivers, and providers have all seen increased levels of satisfaction – patients have reported improvements in the quality of life and health; family caregivers have seen the demands on them decrease; and nurses have found their work to be more meaningful as they get to spend additional one-on-one time with patients.

Hospitalists

Effective care coordination depends on adequate knowledge about the conditions being treated, the patient's individual needs, the roles of the different providers, and the resources available. Within the hospital setting, physicians designated as hospitalists not only have developed special technical expertise involving conditions that require effective inpatient care, but can also help manage patients with complex health care needs by taking care of, and efficiently managing milestones of their "whole person care." This includes managing both the condition that the patient was admitted for as well as co-morbidities, which can help to ensure that the patient is sufficiently stabilized before he/ she transitions to the next care setting.

A successful hospitalist will need to efficiently coordinate care across providers, while making efficient determinations about the types of health problems that require effective inpatient treatment. For instance, a cancer patient may be treated in the hospital by the oncologist, but see a primary care physician for diabetes management. The hospitalist would be responsible for ensuring that treatment addresses both the primary condition – in this case cancer – and all co-morbidities across levels of care, which include diabetes. Multiple studies have shown that hospitalist care can be associated with shorter hospital stays and lower costs.⁶

Additionally, non-physician staff members may be responsible for assisting in a patient's care. These staff members, sometimes called case managers or care coordinators, are responsible for helping to identify patients with high-risk conditions, assisting with disease management education and/or follow-up, helping patients navigate the health care system, and collecting data on process and outcome measures. Some, usually large, physician offices have their own staff member, but most practices share an external coordinator who follows specific high-risk patients. The intensity of a coordinator's involvement with a patient varies on the severity of each case, but many patients can be empowered to manage their condition.

Guided Care

A team of researchers at John Hopkins developed the interdisciplinary Guided Care model in 2001, which has primary care practices hire a highly skilled nurse to track, assess, and manage patients with multiple chronic illnesses.⁷ One of the nurse's responsibilities is to develop, in coordination with the patient and their support team, an evidencebased care plan that includes all parties' care responsibilities and is distributed to the patient, the patient's family, and the primary care practitioner. Additionally, the nurse will work with the patient and their support team to help identify needed social and community supports.

The Guided Care model has been proven to improve care quality and reduce total costs, rates of hospital admissions, days admitted, and emergency room visits, resulting in a net costs savings that more then offsets the costs of adding a nurse coordinator to the practice. ^{8,9}

Patient-Centered Medical Homes

The Patient-Centered Medical Home (PCMH) is a hybrid care delivery and payment reform model that works to integrate and coordinate care by providing a monthly management fee to support investments in health IT, management tools, and care coordination activities. The medical home is centered on a redesign of primary care delivery supported by enhanced access to clinical information systems that help to integrate care across providers, quality improvement and learning, and initiatives to encourage patient engagement in care. Medical homes can operate independently of ACOs; however, they may work best in conjunction with the ACO payment model. Medical homes receive upfront payments which can help support initial care intervention investments. If paired with an ACO, they would be able to receive shared savings if their efforts at quality improvement and cost reduction are successful (see text box for ACO initiatives building on medical homes).

Research assessing the impact of medical homes has shown that the model increases access to care, promotes prevention, and engages patients in self-management and shared decision-making. Specifically, medical homes can be an important intervention in reducing costly emergency department visits. Research also shows that patients prefer the more active involvement of their primary care physician in disease management. All of this can help lead to increased patient satisfaction, improved outcomes and quality of life, and lower costs.

ACOS BUILDING ON MEDICAL HOME PILOTS

Vermont Blueprint for Health. Vermont is piloting enhanced medical homes in three communities as part of its statewide Blueprint for Health Initiative. The Pilots are working to improve care quality with support from a multi-disciplinary Community Health Team (CHT), which partners with primary care offices, hospitals, and health and social service organizations to better coordinate care across settings. In addition, sites will be aided by expanded health IT capabilities including a clinical tracking system, a statewide health information exchange network, and an integrated prevention action plan based on assessments of community risk factors. The goal of these efforts is to enhance patient self-management and integrate community-wide public health prevention efforts. The multi-payer initiative, which is currently supported by three commercial payers, Medicaid, along with some funding from the state, will begin implementing ACO pilots in 2011.ⁱ

Community Care North Carolina (CCNC). CCNC is another example of the medical home model in practice. CCNC is a nonprofit organization made up of 14 networks and over 4,500 primary care physicians that connects community providers – including hospitals, health departments, and department of social services – with primary care physicians. Physicians are paid a monthly payment in return for managing patient care for more than one million Medicaid enrollees, serving as a single access point for patients and providing 24 hour access to care, as well as participating in quality improvement, disease management, and prevention activities. The state Medicaid program pays physicians a per member per month (PMPM) fee in addition to FFS payments at 95 percent of Medicare payments.

CCNC aims to improve care quality, utilization, and cost effectiveness of chronic care. Originally a Medicaid program that provided some care to uninsured populations, the program was recently expanded to include Medicare and Medicaid dual eligibles and will expand within three years to the general Medicare population through the Medicare Health Care Quality Demonstration. As discussed in previous sections, under the demonstration, providers will have an opportunity to share with CMS any savings they achieve through their physician-directed care coordination program. The demonstration will test the impact of a physician-directed care coordination program – supported by a regional physician pay-for-performance program, health IT, and a common set of quality measures across multiple payers – on care quality and efficiency.

Early evaluations of the model suggest that it can result in significant cost savings and improvements in care quality. For example, conservative analyses estimate annual savings of \$60 million in fiscal year 2003 and more than \$160 million in fiscal year 2006. Reductions in emergency department utilization (23 percent less than projected), outpatient care (25 percent less than projected), and pharmacy (11 percent less than projected) were the largest drivers of these savings. The model has also shown improvements in the quality of care, including improvements in asthma control, which was one of the first CCNC focus areas.ⁱⁱ

i. Hester J, Lewis J, McKethan A, "The Vermont Accountable Care Organization Pilot: A Community Health System to Control Total Medical Costs and Improve Population Health", The Commonwealth Fund, May 2010: http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2010/May/The-Vermont-Accountable-Care-Organization-Pilot-A-Community-Health-System-to-Control.aspx
 ii. "CCNC/Access cost savings – State Fiscal Year 2007 Analysis," Mercer, February 2009: www.communitycarenc.com/pdfdocs/mercer sfy07.pdf

5.2: CONDITION OR POPULATION SPECIFIC INTERVENTIONS

Interventions that are targeted to specific patient populations and clinical areas typically have a greater impact on quality improvement and cost containment than broader approaches. In particular, ACOs should consider interventions that address the growing chronic disease burden. Chronic diseases are responsible for 75 percent of overall health care spending, with nine of 15 diagnoses at hospital admission directly related to chronic disease among older Americans.¹⁰ Given that every portion of the population has a growing prevalence of chronic disease, gaining control over chronic disease is one of the most essential elements of any health care delivery reform.

ACOs may consider using predictive modeling such as high utilization, complexity of conditions, or other clinical and socioeconomic characteristics to better target their interventions and improve return on investments. Continual development of analytical capabilities and better evidence on which interventions are most effective for specific populations will be important as ACOs continue to develop and implement their reforms.

Below we outline several promising examples of targeted interventions that can reduce hospitalizations for specific populations and prevent complications associated with chronic disease.

Chronic Disease Management

The underlying goal of disease management is to reduce the burden of disease and improve health outcomes by preventing complications and emphasizing better prevention and care management. These efforts are particularly beneficial for frail patients and those with multiple chronic conditions and can result in improved patient and family satisfaction with care and reduced costs. Necessary components of a successful disease management program include the ability to identify and monitor highrisk individuals, apply evidence-based practice guidelines, coordinate care between providers, and encourage patient self-management through education and patient tools. The range of disease management services can include timely initiation of ancillary health services, patient monitoring and empowerment, and coordinating community services.

When these services are delivered in a timely manner, they can reduce preventable complications, emergency department visits, length and frequency of hospitalizations, and unnecessary gaps in care. In particular, diabetes, asthma, and congestive heart failure (CHF) are all areas that have been shown to be amenable to disease management activities.

For example, the Camden Citywide Diabetes Collaborative was developed by the Camden Coalition of Healthcare Providers to address growing overutilization of emergency room care due to conditions related to diabetes. Efforts include steps to increase the capacity of communitybased primary care practices and medical day programs, support diabetes self-management, and improve care coordination. The collaborative has helped convert ten community-based primary care practices into certified Patient-Centered Medical Homes, develop electronic health records and a diabetes registry, and support provider education to standardize diabetes care.¹¹

The use of an asthma nurse specialist has also been found to reduce total hospitalizations and readmissions for asthma. Specifically, asthma nurse specialists assisted primary care physicians in simplifying asthma care programs, completing daily "asthma care" flow sheets while the patient was in the hospital, educating patients in asthma self-management and developing personal asthma care plans, and providing outpatient follow-up. These activities resulted in a 60 percent reduction in total hospitalizations and a 54 percent reduction in readmissions for asthma, which amounted to \$6,462 in savings per patient in direct and indirect health care costs.¹² Other successful asthmafocused disease management activities have included web-based coaching and home-based health action plans.¹³

There are also many CHF disease management programs. Most focus on patient education by nurses, advanced practitioners, or pharmacists with follow-up education over a period ranging from six months to three years. Experienced cardiovascular nurses at the Jewish Hospital at Washington University Medical Center provided high-risk, elderly CHF patients with intensive education about CHF and supported efforts to encourage treatment compliance, including individualized dietary assessment and instruction by a registered dietitian, discharge planning with social service personnel, medication analysis and reconciliation by a geriatric cardiologist, and intensive follow-up after discharge with the hospital's home care services. They found this intervention lowered hospital readmission rates by approximately 22 percent for all causes within 90 days of discharge and 55 percent for readmissions related to CHF. The intervention also resulted in a 36 percent reduction in length of hospital stay, lowering cost of care by nine percent and producing a return on investment of 1.37 percent. Like disease management programs for diabetes and asthma patients, appropriate program design and targeting can greatly influence the success of the intervention.14

It should be noted that for all these interventions, the evidence base has been mixed, in some cases producing significant cost savings, while in others resulting in no statistically significant changes. Importantly, studies have found that disease management programs that target higherrisk patients tend to result in a greater likelihood of reduced costs and utilization compared to programs that provide more modest interventions targeted to a patient base with mixed disease severity. Thus, ACOs should carefully consider which interventions have the greatest chance of success given their unique patient population. It will also be critical for ACOs to develop multiple initiatives to better ensure the ability to find those that are successful.

Medication Management

Interventions that address non-adherence to medications and better medication management represent an additional opportunity for generating savings while improving patient care. It is estimated that patient non-adherence to medication costs the health care system up to \$290 billion a year.¹⁵

Medication management can take many forms. It can involve a care team that includes the prescribing physician, pharmacist, or a staff member who keeps in contact with the patient. In one example, hypertension patients saw an increase in controlled blood pressure rates with web-based pharmacist care. The program began with a telephone visit between the pharmacist and the patient. Then an action plan was introduced and shared with the patient and prescribing physician. Secure web-based communication continued every two weeks until blood pressure was controlled.¹⁶

Newly evolving technologies can help to remind patients to take their medication, monitor patient adherence, and relay data back to the provider. These technologies in support of medication management programs can also inform physicians of the full costs of a treatment. For instance, CCNC (see text box above for more details) created a prescription advantage list, which ranked drugs based on cost to encourage the use of lower-cost medications when appropriate. CCNC reports lower drug spending and an estimated savings of \$1 million per year due to the use of the prescription advantage list.¹⁷

Targeting Individuals with Multiple Chronic Conditions and Functional Limitations

As individuals with both chronic conditions and functional limitations represent 14 percent of

the population but 46 percent of health care expenditures, targeted interventions for this group represent a high-yield strategy.¹⁸ Individuals with chronic conditions and functional limitations (difficulties walking, performing activities of daily living, etc.) on average spend three times what others spend on health care. A great deal of this spending is dedicated to inpatient services and prescription drugs, demonstrating an opportunity for greater care coordination.

CMS is currently operating a demonstration for post-acute care (PAC) payment reform. The demonstration developed the interoperable, electronically-based Continuity Assessment Record and Evaluation (CARE) tool to measure health and functional status of Medicare PAC and hospital discharges. CMS will use the data from the tool and demonstration to examine differences in costs and outcomes across PAC provider types. The results of the demonstration will also be used to reform payment for skilled nursing facilities, home health, inpatient rehabilitation facilities, and longterm care hospitals. As data collection on chronic conditions and functional limitations becomes more standardized, robust, and electronic, and as payment reform for post-acute settings improve provider ability to coordinate care, ACOs may find cost-savings by focusing on frailer individuals leaving acute or post-acute settings.¹⁹

A pilot from Boeing (the Intensive Outpatient Care Program) demonstrated that targeting patients with severe chronic conditions for a medical home intervention can yield cost-savings, improved physical and mental functioning, and reduce number of work days missed. Because the pilot simply targeted the highest-cost group for intensified coordination, it did not require longterm delivery system re-organization, large-scale health IT implementation, or years of change to see cost-savings. Similarly, Geisinger Health System implemented case management programs for their highest risk patients, drawing on nurse-case managers. Geisinger attributes some of its success in slowing spending growth to this program. Another example of targeting high-cost individuals with multiple chronic conditions and functional limitations is the Care Level Management model (CLM). Care Level Management, a vendor of physician services, contracts with plans on a combination of per member per month and FFS. CLM patients have difficulty getting to medical offices, and CLM specializes in physician home visits and constant physician availability. With its focus on frail patients in the top percentiles of spending, CLM has found that its services can reduce admissions by 60 percent.²⁰

5.3: PATIENT ENGAGEMENT IN CARE

For ACOs to have a positive impact on health care spending, they must encourage active patient participation in their own health in addition to rewarding effective provider efforts to improve quality and reduce costs. ACOs in tandem with their respective payers can play an important role in encouraging patients to make choices that are more consistent with high quality and efficient care. Below we discuss promising strategies that encourage the use of cost-effective primary care and preventative services that together can delay or prevent the onset of costly chronic conditions, even under the limitations imposed by the mixed incentive structures of the traditional FFS Medicare.

Patient Education and Shared Decision-Making

A fundamental tenet of delivering high-value health care is ensuring that patients have access to information that can help them make informed decisions about their health care. Patients who are knowledgeable about and engaged in their treatment are more likely to continue treatment and adhere to provider advice, which ultimately improves overall outcomes, enhances patient satisfaction, and reduces avoidable complications. Patients who receive either a web-based or paperbased decision aid containing information about prostate cancer screening concepts, benefits, and risks have been found to be more informed and more engaged in the screening decision than patients who did not receive a pre-visit education.²¹

The Dartmouth-Hitchcock Medical Center's Center for Shared Decision Making is a leader in engaging patients to understand treatment options, outcomes, risks, and benefits. The Center uses an array of condition-specific educational videos, decision-making tools, and counseling to support informed decisions about treatment. Such services and tools guide patients towards high-quality, costeffective, and patient-centered care.

Wellness and behavior change programs can also serve to lower health care spending and improve patient well being due to reductions in emergency room visits and inpatient stays. Such programs encourage patients to improve their health by providing patients with education on self-care and health maintenance strategies, and professional support to carry out these recommendations. For example, for patients with chronic asthma, a patient self-management plan developed in collaboration with a physician can help identify appropriate responses to specific symptoms based on established care guidelines. Studies comparing self-management to usual care have found that patients monitoring their own asthma not only had better outcomes, but saved considerably over those in standard care with a primary doctor.22

Patients informed of the likely outcomes and overall costs of treatment options make better and often lower-cost decisions about the care that they need. This includes care planning for serious illnesses near the end of life, the cost of which can vary dramatically by region. A recent Dartmouth study found that patients in high-spending regions received about 60 percent more end-of-life care due to differences in the frequency of physician and specialist visits, tests, and hospitalizations. Yet higher spending did not lead to higher quality of care, greater access to care, improved health outcomes, or higher patient satisfaction.²³ For instance, 30 percent of seriously ill patients reported that they would rather die than live permanently in a nursing home,²⁴ and 28 percent of patients with advanced heart failure would trade one day of excellent health for another two years in their current state.²⁵ Increased attention on end-of-life planning can improve patient, family, and caregiver satisfaction, improve patient quality of life, and reduce utilization while staying consistent with patient wishes.

Another excellent example of patient education is the Everett Clinic, which employs hospice nurses in its primary care clinics to provide intensive case management and end of life planning, including promoting palliative care. The program has resulted in significant reductions in readmission rates and has increased the use of hospice and home care services among elderly patients who are chronically ill. Evaluations of the program found that it resulted in a 35 percent reduction in readmissions 60 days prior to death.²⁶

Other well-documented examples of effective end-of-life care management include treating cancer pain and cancer associated depression; for instance, lung cancer patients who experienced continuity of care across the outpatient to hospital settings were less likely to spend time in the intensive care unit prior to death.²⁷

Value-Based Insurance Design

Financial rewards and other incentives for patients may significantly leverage ACO delivery reforms. ACOs can work with their health plans to encourage active patient engagement in their care by designing benefits to reward cost-saving, high-value behavior. One approach is for plans to restructure their cost-sharing requirements to support the utilization of cost-effective primary care and discourage the use of costly and ineffective care by lowering or eliminating co-payments for primary care visits or instituting tiered drug benefits. In the latter circumstance, plans can implement drug benefits that make effective drugs available at low or no cost for specific populations, as well as use formularies to encourage patients to switch to more cost-effective drugs (e.g., generics). These efforts can be particularly beneficial to patients with chronic conditions. Many chronically ill patients incur significant out-of-pocket costs, which can discourage the use of important, high-value health services and can serve as barriers to seeking preventative care.

The City of Asheville implemented benefit reforms in conjunction with disease management programs. Specifically, the city waived co-payments for diabetes-related drugs and devices for patients who agreed to participate in a diabetes education program administrated by local pharmacists. An evaluation of the program revealed that the expanded pharmaceutical care services reduced total mean direct medical costs by almost \$700 per patient per year.²⁸ Given the promising early results, the program has expanded to other chronic conditions, including asthma.

Similarly, benefit design may enable patients to share in the savings when they use ACO providers that have demonstrated better results in both quality and cost of care. Patients who use a specialist preferred by an ACO because the specialist has demonstrated lower complications and lower overall costs could potentially see significant reductions in their out-of-pocket costs.

Geisinger Health System's ProvenCare is an example of a successful benefit design program that relies on strict evidence-based practice standards, pay-for-performance principles, accountability through capitated payments, patient engagement, and other checks and balances to improve quality while lowering costs. By diligently adhering to evidence-based practice guidelines and building accountability into their delivery system, ProvenCare has lessened the average total length of stay, improved the 30-day readmission rate by 44 percent and drastically reduced complications and infections.²⁹

Other studies have also demonstrated that reducing out-of-pocket costs for evidence-based treatments results in an increase in patient adherence to medication plans and/or reduction in overall health care costs.³⁰

5.4: INFRASTRUCTURE AND ORGANIZATIONAL REDESIGN

To support the reforms discussed above, ACOs will need to invest in infrastructure and adopt new organizational tools and strategies. This includes investments in health IT, which can help providers monitor progress, evaluate performance against targets, and make real-time program adjustments based on these findings. Such investments need not involve comprehensive electronic records; many successful care transformation initiatives have made limited, focused investments in patient registries oriented toward closing particular gaps in quality. As the ACO's clinical improvement objectives become more sophisticated, the data capabilities can be enhanced as well. A robust health IT infrastructure with data management systems can also help lead to more advanced care integration and coordination strategies, such as disease and utilization management and Patient-Centered Medical Homes. That said, investments in health IT should be viewed as catalysts for the delivery transformations described throughout this toolkit, as health IT investments alone are rarely a means of long-term savings.

In addition to infrastructure investment, ACOs will also need to implement strong process management and cultural reforms to help support the more efficient and effective delivery of care. These operational and organizational improvements are particularly important for clinical transformations in hospitals and other providers where strong leadership will be necessary to address the inefficiencies and variation in care delivery that can lead to low-quality care and costly complications. Strong leadership will especially be needed in provider settings under traditional FFS payments where incentives to reduce costs and potentially utilization are not always clear. It is important that organizational managers see process improvements as a means not only of achieving the potential savings described throughout this section, but also for reducing overhead costs which can lead to additional savings.

Many of these process and organizational improvements can be implemented fairly quickly, so ACOs may want to consider implementing these reforms first as they also ramp up other delivery reform activities. Some examples of organizational redesign to improve care and increase value for an ACO can include providing detailed management reports for clinicians to target areas of improvement, strengthening non-physician workforce for costeffective care coordination, and improving work environments to reduce workforce turnover.

One specific example of a relatively simple organizational redesign that quickly yielded higher quality care is the Institute of Family Health's electronic health record (EHR)-based clinical decision support system. Although EHRs were already in place, practices found that they had very low pneumonia vaccinations for patients over 65. The Institute decided to implement an automatic vaccination reminder for all patients over the age of 65. Vaccination rates for the targeted population rose from less than ten percent to about 90 percent with the decision support redesign. In addition to automatic reminders, quick safety procedure checklists have been demonstrated as a low-cost organizational solution to reducing hospital-acquired infections.

Below we discuss other infrastructure and organizational redesign examples in more detail.

Health IT

Providers rely on timely clinical information to inform clinical improvement and drive practice redesign. Health IT can refer to any number of electronic systems that facilitate the collection, organization, and sharing of medical information electronically, including EHRs, electronic medical record (EMRs), health information exchanges (HIE), and personal health records (PHRs). Implementing these systems is only the first step; to realize cost savings and improve quality, ACOs must actively use this information and these systems to support disease management and care coordination activities and better target their efforts at high-risk patients who can benefit the most from these efforts.

The Indiana Health Information Exchange (IHIE) is one of many successful examples of using health IT to improve the quality, safety, and efficiency of the care. IHIE focuses on several core services, including: a clinical messaging service; a clinical repository service; and a chronic disease, preventive care, and quality reporting service. By connecting nearly 70 hospitals, long-term care facilities, and other Indiana health care providers involving more than 19,000 physicians, IHIE is able to deliver lab results, reports, medication histories, and treatment histories in real-time for over six million patients. Previously, this information was stored in various physician offices or hospitals but now is able to follow patients, regardless of where they are receiving their care.

The providers in Indiana are also using health IT to drive quality improvement and adherence to evidenced-based medicine. Through the Quality Health First (QHF) program, which was developed and is administered by IHIE, providers receive quality reports comparing their performance to quality benchmarks and to their peers. The reports – based on information from health insurance claims, point of care data from the physician's office, and clinical information – are then used to calculate performance payments. Both public and private payers, including Medicaid and Medicare through the Medicare Health Care Quality Demonstration Program, are contributing data. Although the program is voluntary, QHF has seen broad participation by physicians. This is partly because the program provides physicians with individual, patient-specific alerts that inform physicians when measures are not being met in specific patients and what action is needed.

Another example are providers at Geisinger Health System who developed a "bundle" of best practice measures for diabetes and are using an electronic registry derived from a fully integrated EHR to improve physician performance in diabetes care. Physician performance was then compared to national benchmarks and to peers through an audit and feedback program that included computerized reminders. Physicians that met or improved on the diabetes bundles criteria received payment bonuses. Evaluations of the program found that it resulted in significant increases in vaccinations for pneumococcal disease and influenza (by 43 percent and 29 percent respectively). The percentage of patients with ideal glucose control (HBA1c<7.0) and blood pressure control also improved (by 8 percent and 11 percent respectively). Finally, the number of patients receiving all nine "bundled" measurements increased by 170 percent, from 2.4 percent to 6.5 percent.31

Organizational and Clinical Redesign

Many health systems have real potential to achieve savings by redesigning their organization to realize efficiencies in both clinical and administrative processes. By focusing on improving patient experience through better administrative systems (e.g., more efficient scheduling processes), more efficient supply systems, improved data sharing for more efficient clinical practice, and better overall system management, ACOs may be able to improve patient care while lowering costs. Redesigning organizational processes should be based on an analysis of each individual ACO's current organizational system and identified inefficiencies. Models have been developed to help break down care delivery into manageable parts to identify the truly functional units of clinical care. These units, described as "clinical microsystems," could help ACOs better target their quality and cost interventions in a more efficient manner.³²

Discussed below are some examples of systems that have borrowed organizational designs from other industries to make their own processes more streamlined, efficient, and patient-focused:

ThedaCare, a community health system in Northeast Wisconsin, uses process redesign methods to fully integrate their clinical and administrative processes. Lean manufacturing techniques, developed by Toyota, have helped maintain a focus on continuous quality improvement and a reduction in "defects," which can include inefficiencies in care processes or problems in care quality. Using data to drive process change, staff members identify problems, track progress towards improvement goals, and ensure that once goals are achieved the improvements can be made sustainable.

Specifically, ThedaCare seeks to improve a patient's care experience by decreasing defects and wait time by 50 percent per year and aims to increase productivity by 10 percent per year. To accomplish these goals, ThedaCare sponsors rapid improvement events, which take place over seven weeks and work to identify and eliminate organizational inefficiencies. By working collaboratively with staff members to develop and test new work processes, they gain more buy-in and commitment from staff members across the organization. Staff members are also provided with forms that help identify and resolve any problems as new work processes are rolled out.

Another organization that used organizational redesign to achieve real savings is the Seattle Children's Hospital. Seattle Children's Hospital also used a process redesign strategy used by Toyota, known as continuous performance improvement (CPI). CPI focuses on the patients' entire experience at the hospital to determine ways to not only lower costs, but also improve patient experience. For example, improving the process to sterilize surgical instruments allowed the hospital to respond to an increased need for additional procedures without having to invest in new facilities and staff; additionally, improving scheduling processes helped reduce the wait time for a MRI from nearly a month to just one or two days. Other CPI-identified redesigns were found to significantly improve patient satisfaction, including beginning to identify patient goals and improving communication, as well as assembling outpatient services upon admission while simultaneously reducing inpatient stays and increasing the number of possible visits.

To try and align hospital staff members behind CPI initiatives, Seattle Children's Hospital holds regular workshops that include doctors, nurses, administrators, and representatives of patients' families to walk through a typical patient experience to help identify areas of possible improvement. This collective process has helped ensure there is ownership of these initiatives by not only hospital leadership but also by physicians and patients.

CONCLUSION

This section discusses examples of some of the many clinical transformation activities that can be undertaken to achieve meaningful improvements in the quality and efficiency of care for ACO patients. Because no single intervention may be substantial and robust enough to lead to the kind of populationlevel improvements in care that are needed to achieve ACO quality and cost benchmarks, these efforts to improve care may be most effective if they are implemented in a coordinated and integrated fashion.

Nearly all of the delivery transformation efforts described in this section are enabled through health IT – such as electronic medical records, patient registries, and electronic decision support systems – which can help to identify high-risk patients, encourage better information sharing and coordination of treatments, and assist providers in making high-value, evidence-based health care decisions. By layering multiple reforms, ACOs will have a greater chance of driving system-wide change that can lead to better quality and lower costs and justify health IT investment, which alone are unlikely to be long-term cost-savers.

The steps to change the way care is delivered are difficult and require not only new kinds of financial investments but also time and effort on the part of leaders and clinicians. In effect, these specific steps can and should add up to meaningful cultural change in an organization, helping create the alignment between financing and delivery reform that is key to successful ACO implementation. In turn, these initial steps create a stronger organizational foundation for further, more sophisticated steps to continue to achieve measurable improvements in quality of care and efficiency.

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Part 6

Legal Issues for ACOs Katherine Funk, Chris Janney



ACCOUNTABLE CARE ORGANIZATION

PART 6: LEGAL ISSUES FOR ACOS

One of the often cited hurdles to the formation of ACOs is the legality of their formation and operation. This section focuses on five of the most likely legal issues that elements of ACO implementation raise (e.g., organizational model, flow-of-funds, data sharing):

- Section 6.1: Federal antitrust law;
- Section 6.2: Federal physician self-referral (or "Stark") law;
- Section 6.3: Federal health care program antikickback law;
- Section 6.4: Federal services reduction civil monetary penalty law; and
- Section 6.5: Federal tax law.

This section also touches briefly on state antitrust laws, state fraud and abuse laws, federal and state false claims acts, government managed care regulations, corporate practice of medicine, and state insurance law.

The legal topics covered in this section are by no means an exhaustive list of legal barriers facing ACOs. Among other things, there are a wide variety of actual and potential ACO "models," each of which raises a unique set of legal issues. Further, each state has its own, specific set of potentially relevant fraud and abuse and other laws and regulations.

Readers should not construe this document as constituting legal advice. Any organization that is considering participating in an ACO should engage legal counsel to review the particular aspects of the proposed structure and operations for compliance with all relevant federal and state laws. In addition, the legal guidelines discussed below are not static; new rules and precedents applicable to ACOs are expected in the coming year. As noted in the discussion below, potential changes may include applicable guidance from state and federal agencies, rulemakings, Secretary "safe harbor" rules under ACA, and even legislative reform.

6.1: FEDERAL ANTITRUST LAW

Overview

The antitrust discussion in this chapter reflects the antitrust analysis of the activities of ACOs within commercial insurance markets. There are few if any antitrust issues that arise in the Medicare/Medicaid markets because the payer (the government) sets the rates and the rates are transparent. Antitrust is included in this toolkit because it is likely (indeed it is already happening) that ACOs forming in response to ACA will want to also transact with commercial payers. And of course, there will likely be ACOs that form for the primary purpose of engaging with commercial payers.

Measured against other health care industry legal issues, the antitrust issues arising out of ACO formation and operation are modest. In part, the modest level of antitrust risk is due to the high degree of congruence between the principles underpinning the antitrust analysis and the stated goals of ACOs under ACA and as contemplated by Brookings/Dartmouth. Antitrust laws are premised on the principle that competition generally benefits consumers by producing the best combination of quality, goods, and services at the lowest prices. Compare with the premise of ACOs: that patient care integration will lead to better care at lower cost. Additionally, the Federal Trade Commission (FTC) and the Department of Justice (DOJ) have produced a great deal of guidance on provider integration. Nascent ACOs should use this guidance to construct organizations that are both lawful and that achieve the promised cost-savings and improved outcomes.¹ Much of this guidance is available on the FTC website at www.ftc.gov/bc/healthcare/ index.htm. Simply put, the antitrust issues raised by the formation and operation of ACOs are both navigable and manageable.

Review of Basic Antitrust Concepts²

Before undertaking an antitrust analysis of the transactional relationships that an ACO is likely to encounter, we first introduce and discuss the two principal antitrust categories into which conduct is divided: (1) "rule of reason"; and (2) *"per se."*

The Rule of Reason

The vast majority of conduct is analyzed under the "rule of reason." A fact-finder will examine all of the facts and circumstances surrounding the arrangement at issue to determine whether, on balance, the anticompetitive effects of the arrangement substantially outweigh its procompetitive benefits. Key considerations include the following:

- Whether the arrangement at issue has the potential to achieve significant efficiencies (e.g., cost savings that are passed along to consumers, or more robust competition);
- Whether the pro-competitive efficiencies of the arrangement outweigh any anticompetitive effects; and
- Whether the arrangement involves any agreements that usually are considered anticompetitive (e.g., agreements on price) and, if so, whether those agreements are reasonably necessary to achieve the efficiencies sought.

The Per Se Rule

The "per se" rule typically is reserved for conduct that is known to have substantial anticompetitive consequences — such as "naked" price fixing (arrangements whose primary purpose is to fix prices) — and few, if any, beneficial attributes. Because such conduct is *per se* illegal the parties are not given an opportunity to justify their conduct (e.g., "the prices we agreed upon were low and the payer saved money"). If an ACO is constructed and operated with the pro-competitive goals and intentions promulgated by Brookings/Dartmouth, the antirust risk for that ACO will likely be very manageable. But because ACOs may contain participants who are direct competitors of one another, there is a risk that such participants might share information that could adversely affect competition in transactions outside the ACO (e.g., two hospitals that are members of the same ACO allocate non-ACO patients in the same ZIP code). Under certain circumstances, such conduct could rise to *"per se"* unlawful. In many if not most situations, however, there are relatively simple and straightforward procedures that can be put in place to lessen the likelihood that unlawful behavior takes place.

Applying the Antitrust Concept to an ACO

ACOs raise two main antitrust questions:

- Whether the ACO is an arrangement to enable its providers to fix prices – or whether it is an integrated joint venture that has the potential to improve quality and lower costs.
- Whether the formation of the ACO creates market power or allows it to be exercised in new ways.

These questions will generally arise under the following headings:

- Pricing Agreements
 - Provider fee negotiations with commercial payers
- ACO Market Power
 - Market allocation issues
 - Provider exclusivity

Pricing Agreements

Provider Fee Negotiations. In general, antitrust laws prohibit competing providers from jointly negotiating their reimbursement rates with commercial payers.³ This type of conduct can rise to *per se* illegal price fixing. There is, however, an exception where the providers have integrated for a valid purpose, e.g., improved outcomes, and where joint negotiations are necessary to the achievement

of those efficiencies. In other words, if providers have integrated their services to create a product or service that none of the participants alone could produce, or produce as efficiently, antitrust law generally will permit that joint venture, so long as the integration does not create or enhance market power (see discussion below for potential suggestions to mitigate this problem).

The FTC and the DOJ have found that, when negotiating provider fees or remuneration from payers, the pro-competitive aspects of the following two types of provider networks or joint ventures outweigh the anticompetitive effects: (1) the substantial financial risk model; and (2) the clinical integration model.

Substantial Financial Risk. Financial risksharing gives providers the incentive to cooperate in controlling cost and improving quality of care. Providers that organize around substantial financial risk-sharing closely resemble common organizational forms such as LLCs, partnerships, etc. As a threshold matter, determining whether an arrangement does, in fact, involve the sharing of substantial financial risk requires a review of the particular facts. At a minimum, the risk of loss must be real and that risk must be shared across the spectrum of providers involved in the arrangement. "Risk pools" in which individual providers bear risk, but do not share risk generally, will not suffice. While risk arrangements can take a variety of forms, most typically include some combination of the following: (1) capitation; (2) a substantial withhold;⁴ (3) a percentage of premium; (4) global fees or allinclusive case rates; and (5) cost and utilization targets. Finally, in their Guidelines, the FTC and DOJ recognize that other types of risk-sharing arrangements may exist, and that they will consider "other arrangements through which the participants . . . may share substantial financial risk in the provision of medical services through the network."5

Clinical Integration. The clinical integration model perhaps most closely resembles the standard ACO, i.e., that of financially separate providers who come together to better treat patients by integrating their clinical practices. A clinically integrated network is one that *can*⁶ engage in joint pricing or collective negotiations without sharing substantial financial risk in the manner described above. Such arrangements can lawfully engage in joint negotiations with payers if they include "an active and ongoing program to evaluate and modify practice patterns by the network's physician participants and create a high degree of interdependence and cooperation among network participants."⁷

So what does this mean? There is no single way to structure a clinically integrated network. This flexibility is an asset. Rather than a "one size fits all" approach, clinically integrated networks can conform to the demands and requirements of their respective communities and the other legal restrictions faced by providers, while also staying within the broad bounds of the antitrust laws. While there is no "cookie cutter" structure, in the Guidelines the FTC and DOJ do provide guidance on the structural pillars that clinically integrated networks *often* have:

- Mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care;
- Selectivity in choosing network physicians who are likely to further these efficiency objectives;
- The significant investment of capital, measured in both monetary and human terms, in the necessary infrastructure and capability to realize the claimed efficiencies.

As clinically integrated networks become more widespread, there will likely be a longer and more varied list of "common" pillars. For example, where an ACO is organized around primary care physicians, the measure of capital investment may be organization-wide rather than on an individual doctor basis. This is important where the initial capital required to form an ACO is significant and the physicians do not individually have the financial resources to make significant investments.

In addition to the pillars, the Guidelines also provide examples of the types of processes that clinically integrated networks have utilized to implement the pillars:⁸

- Electronic health records;
- Case management, pre-authorization (at least of some services), and concurrent and retrospective review of inpatient stays;
- Development of practice standards and protocols to govern treatment and utilization of services, and active review of the care rendered by each doctor in light of those standards and protocols;
 - Regular evaluation of both individual physician's and the entity's aggregate performance with respect to those goals;
 - Modification of individual physician's actual practices, where necessary, based on those evaluations;
 - Physicians who fail to adhere to the standards and protocols will be subject to remedial action, including the possibility of expulsion/termination.
- Reports to payers on the cost and quantity of services provided, and the group's success in meeting its goals; and
- A medical director and support staff to handle the above functions and to coordinate patient care in specific cases.

Not every ACO will have the desire or financial capability to implement all of these processes.⁹ Again, there are no hard and fast rules as to how many of these processes a network must adopt in order to be deemed "clinically integrated." Clearly, the more of these types of processes that are

adopted the more secure a network should feel that it is operating within the boundaries of the law.

Market Power

The assumption that goes along with financially integrated and clinically integrated networks is that the networks intend to negotiate as a collective with commercial payers. As stated above, where a network achieves substantial financial integration or is clinically integrated, it is able to avoid the antitrust issues typically present where competitors act in concert with one another (i.e., Section 1 of the Sherman Act).

Recall, however, that coordinated pricing between competitors is only the first of two antitrust questions that are put to provider networks. Even where the coordinated pricing is permissible, the integration - whether financial or clinical - of a significant number of providers implicates the second antitrust guestion: whether the formation of the ACO creates market power or allows it to be exercised in new ways. Market power is the ability to raise prices above the competitive level or exclude competitors from the market. Courts usually look to market share as an indicator of market power. Whether a provider organization has market power will vary depending on the size of the organization and how many competing providers are in a particular market.

A finding of market power first requires a definition of the relevant product market and the relevant geographic markets.

Examples of product markets might be:

- Primary Care Physicians
- Specialists (e.g. Orthopedists, Urologists, Neurologists, Child Psychiatrists, etc.)
- Multi-Physician Organizations
- Hospitals

Examples of geographic markets include:

- Hospital referral areas
- Metropolitan statistical areas
- City
- County

The relevant product market in which an ACO competes will depend on the range of services offered by the ACO. There are a couple of "short-cut" questions that ACOs can utilize to make a high-level determination of market power concerns:

- Once the ACO is created, who remains to compete with it?
- Who can a payer turn to for the same services as those offered by the ACO?

The geographic market analysis focuses on where, as a practical matter, patients could go if the participants in the ACO raise their prices above competitive levels. For some services (especially complex, tertiary care services), the relevant geographic market could include other providers offering similar services although located some distance from the providers in the ACO. Once the relevant product and geographic markets are defined, the next question is whether the ACO has attained sufficient market power such that it could behave anti-competitively. Note that even assuming that a market share analysis revealed high market shares in properly defined product and geographic markets, it does not necessarily mean that the joint venture is unlawful. As the Guidelines¹⁰ note:

. . . [I]n assessing the likely competitive effects of a multi-provider network, the Agencies are particularly interested in the ability and willingness of health plans and other purchasers of health care services to switch between different health care providers or networks in response to a price increase, and the factors that determine the ability and willingness of plans to make such changes. The Agencies will consider not only the proportion of the providers in any relevant market who are in the network, but also the incentives faced by providers in the network, and whether different groups of providers in a network may have significantly different incentives that would reduce the likelihood of anticompetitive conduct. If plans can contract at competitive terms with other networks or with individual providers, and can obtain a similar quality and range of services for their enrollees, the network is less likely to raise competitive concerns.

Addressing concerns about market power: Avoiding or limiting provider exclusivity. Provider exclusivity (to a single network, to a single payer or ACO) can create antitrust problems when the providers involved in the exclusivity arrangement constitute a substantial percentage of the providers in the relevant geographic market. This is true even when the exclusivity carries a substantial benefit (e.g., a stable network of providers committed to achieving cost-containment goals) because, in certain markets, there may be few, if any, providers left for the remaining networks or insurers. While concerns about exclusivity will vary from case to case, as a rough rule of thumb, exclusive networks which consist of greater than 35 percent of the providers in the market may raise antitrust concerns. The Guidelines have established a 20 percent threshold for exclusive physician networks seeking to qualify for "safety zone" treatment.¹¹ Failure to adhere to the safety zone percentage does not necessarily mean that the ACO will violate the antitrust laws, but it may mean that the network will be scrutinized more closely. All things being equal, exclusivity is generally more of a concern in rural markets than in more urbanized markets because, in a rural market, there may be fewer options available for payers (or networks) seeking to contract with providers.

Exclusivity is sometimes not explicitly stated in an agreement. Exclusivity can be expressed in other ways, such as in a "right of first refusal" clause, or it can be inferred from the circumstances (e.g., physicians in an IPA refuse to contract directly with payers, even though their IPA agreement states that their participation is on a non-exclusive basis). The Guidelines describe certain factors which tend to indicate that a network arrangement is truly non-exclusive:¹²

- Viable competing networks or managed care plans with adequate physician participation currently exist in the market;
- Physicians in the network actually individually participate in, or contract with, other networks or managed care plans, or there is other evidence of their willingness and incentive to do so;
- Physicians in the network earn substantial revenue from other networks or through individual contracts with managed care plans;
- The absence of any indications of significant participation from other networks or managed care plans in the market; and
- The absence of any indications of coordination among the physicians in the network regarding price or other competitively significant terms of participation in other networks or managed care plans.

Notably, the Brookings/Dartmouth ACO model assumes that primary care physicians will be "exclusive" to one ACO, but that specialists will not be exclusive. Whether the exclusivity of primary care physicians raises any market power issues depends upon a variety of factors, including the number of other primary care physicians in the relevant geographic market. The prevailing assumption, however, is that the exclusivity of primary care physicians is not problematic. Nevertheless, this is an issue that should be reviewed by counsel. Addressing concerns about market power: Alternative payment models. In those situations where an ACO may have market power, using alternative payment models may be a way of addressing concerns. For example:

- The ACO can be established as a separate legal entity and have providers as members. The ACO will not collectively negotiate reimbursement with payers, but will instead negotiate certain financial incentives with payers based upon benchmarking. If the ACO meets or exceeds those benchmarks, the payer will provide some remuneration to the ACO. The ACO will then, pursuant to its membership agreement, make distributions to its members. The providers will continue to operate under their individually established commercial contracts.
- The ACO can involve commercial payers in the formation of the organization. By involving commercial payers in the discussions, the ACO can insulate itself against allegations of exercising market power to drive up reimbursement. Importantly, the ACO would not want to be exclusive to any commercial payer or involve the commercial payer in the business operations of the ACO such that it would have access to competitively sensitive information regarding other payers.

Other Common Antitrust Issues that ACOs May Confront

Market Allocation Within an ACO or Between ACOs

Section 1 of the Sherman Act also prohibits two horizontal competitors from agreeing on the markets, customers or territories each will serve. If they enter into such an agreement, they have committed a *per se* violation of § 1 of the Sherman Act unless they are part of an economically integrated (i.e., risk sharing or clinically integrated) joint venture (e.g., ACO) and the market allocation agreement is reasonably necessary to achieve the pro-competitive benefits of the ACO. In that case, the market allocation agreement will likely be reviewed under the rule of reason. For example, in Statement 9 of the Guidelines, the FTC and DOJ state that:

. . . [C]ompeting hospitals in an integrated multi-provider network might need to agree that only certain hospitals would provide certain services to network patients in order to achieve the benefits of integration. The hospitals, however, would not necessarily be permitted to agree on what services they provide to non-network patients.

As the Guidelines highlight, the antitrust concern in this area arises from information "spillover." For instance, as we briefly remarked upon at the beginning of the chapter, there could be antitrust issues where two hospitals within an ACO attempt to transpose their intra-ACO agreements regarding care rationalization to non-network patient situations.

Problems with Boycotts and Refusals to Deal

In the context of provider contracting (either in networking arrangements or with payers), it is usually difficult, if not impossible, for an excluded provider to state a viable boycott or refusal to deal claim. The antitrust laws were enacted to protect competition, not competitors, and accordingly, the antitrust laws generally recognize that a network has a great deal of latitude in choosing its members.¹³ The antitrust laws are generally much more concerned about networks that have too many providers involved (especially if there is an exclusivity clause) rather than too few. Where the ACO from which the provider is being excluded, however, has market power (e.g., there is only one ACO in the geographic area from which the provider draws patients, or the provider has evidence demonstrating that the defendant specifically intends to harm the plaintiff), provider exclusion

could present a problem. Further, antitrust problems could arise, for example, if a large group of specialists refused to do business with one of four competing ACOs in a metropolitan area.

Nonprofit Institutions Act (NPIA)

If an ACO contains nonprofit institutions, it may be confronted with NPIA issues which are unique to nonprofit institutions (i.e., hospitals, schools and other nonprofit entities). The NPIA creates an exemption from the Robinson-Patman Act, which prohibits price discrimination. The text of the NPIA is found in 15 U.S.C. § 13c, which provides:

Nothing in [the Robinson-Patman Act] shall apply to purchases of their supplies for their own use by schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit.

NPIA issues will most often occur in the context of a nonprofit hospital's purchases of prescription drugs. Many nonprofit hospitals purchase drugs at discounts and, in order to gualify for the discount, they must be able to certify to the drug manufacturer that the purchase is for the hospital's "own use." If the use does not qualify as the hospital's "own use," the manufacturer could be exposed to a price discrimination claim by a purchaser who did not receive the discount. The hospital could also face liability under the Robinson-Patman Act, which precludes sellers from giving, and buyers from receiving, discriminatory prices. The Supreme Court defined "own use" in its 1976 decision in Abbott Laboratories, Inc. v. Portland Retail Druggists Association.¹⁴ The court analyzed the definition of "own use" by examining 10 different categories of hospitals' sales and dispensation of drugs purchased at preferential prices. One such category included "walk-in" customers. In determining that NPIA discounts should not apply to "walk-in" customers, the Court reasoned that:

[t]he extension of [NPIA] to the walk-in customer, who has no present connection with the hospital and its pharmacy other than as a place to have his prescription filled, would make the commercially advantaged hospital pharmacy just another community drug store open to all comers for prescription services and devastatingly positioned with respect to competing hospital pharmacies. This would extend the hospital's 'own use' concept beyond that contemplated by Congress by [NPIA].¹⁵

As hospitals have expanded into health care systems consisting of multiple entities (e.g., home health care, nursing homes, hospices and physicians), it has become increasingly difficult to define exactly what constitutes "own use" by a hospital. For example, is it permissible for a nonprofit hospital to purchase prescription drugs at a discount and then resell them at cost to its affiliated, not-for-profit long-term care facility? The answer to this question is yes. In an Advisory Opinion issued to Presentation Health System,¹⁶ the FTC stated that the NPIA covered a hospital's transfer of drugs it purchased to affiliated nonprofit long-term care facilities. The FTC stated that, in light of the common ownership of the hospital and the long-term care facilities, "[t]he Presentation organization may be regarded as a unit having purchased the pharmaceuticals for its 'own use' comprised of the use by its hospital and its long-term care facilities." Thus, resale of the pharmaceuticals to the long-term care facilities would be exempt as long as they were for the longterm care facilities' own use.17

In an Advisory Opinion issued to Harvard Vanguard Medical Associates, Inc. (HVMA) in December 2001, the FTC stated that HVMA, through its clinic pharmacies, may dispense products purchased under NPIA to the clinic's patients. HVMA is a nonprofit clinic composed of several health care practitioners. HVMA also operates its own pharmacy. The FTC stated that the dispensation of products purchased under NPIA by HVMA pharmacies to HVMA's patients who are under the continuing care of an HVMA physician is acceptable and meets the definition of "own use."

While it is difficult to articulate a bright line rule for the application of NPIA to the gamut of hospital activities, it does seem reasonably clear that if the activity promotes the nonprofit institutions' "intended institutional operation in the care of persons who are its patients," an argument exists that the activity should be protected by the NPIA.¹⁸

Ancillary Service Referrals

Currently, hospitals' ownership of, or affiliation with, ancillary service businesses, such as hospice or home health, creates the opportunity for exclusive referral arrangements. It is likely that this competition concern would be elevated within the ACO model because one of the ways that costsavings can be obtained is by creating efficiencies in the referral relationship. An exclusive referral arrangement is potentially subject to attack under § 1 of the Sherman Act (as an exclusive dealing claim, assuming the hospital is only affiliated with, and does not own, the ancillary service business).

The critical issue under § 1 of the Sherman Act is foreclosure from referrals. If the hospital's percentage of patients needing ancillary services constitutes a substantial percentage of all referrals to ancillary service providers in the relevant geographic market, and those patients are "steered" to the hospital's affiliate or subsidiary exclusively, the potential for antitrust problems could be significant because there may be an insufficient number of remaining referrals for competitors. As a general proposition, however, control of at least 30 percent of the referral market is usually needed before antitrust concerns arise.¹⁹ For example, assume that an ACO in a mid-sized city has within it all of the hospitals operated by a nonprofit religious organization. All of these hospitals also have on their campuses senior living facilities that provide a continuum of care from independent living to skilled

nursing. If the hospitals within the ACO employ more than 30 percent of all geriatric physicians within the metropolitan service area, then it may be the case that the senior living facilities associated with the hospitals will receive a substantial number of referrals from the geriatric physicians, thereby potentially foreclosing referrals to senior living facilities not associated with hospitals within the ACO.

Conclusion

The promise of the ACO model, to reduce costs and improve outcomes, is exactly the type of economic conduct that the antitrust laws seek to promote. Nevertheless, as with any collaboration between competitors or potential competitors, it is important for participants to be aware that the potential does exist for anticompetitive conduct to take place. The purpose of this overview is to alert those who are forming ACOs and those who participate in an ACO of the likely pitfalls, and provide a pathway to navigate around them (see appendix for more information on federal Antitrust statutes).

6.2: FEDERAL PHYSICIAN-SELF REFERRAL (OR "STARK") LAW

The federal physician self-referral law (or "Stark Law") has two basic prohibitions: a referral prohibition and a billing prohibition. Pursuant to the referral prohibition, absent an applicable exception, a physician who has a "financial relationship" with an "entity," or a physician with an "immediate family member" who has such a financial relationship, may not make a "referral" "to" that entity for the "furnishing" of "designated health services" (DHS) for which payment may be made by the Medicare program.²⁰ For example, if a physician has a financial relationship with a hospital, the physician cannot refer any Medicare patients to the hospital for inpatient or outpatient services, both of which are DHS, unless the financial relationship fits into an exception.

Pursuant to the billing prohibition, absent an applicable exception, a health care provider may not bill for improperly referred services. Specifically, an entity that furnishes DHS pursuant to a prohibited referral may not "present" or "cause to be presented" a claim or bill for such services to the Medicare program or to any other individual or entity, including secondary insurers and the patient.²¹ (Thus, in our example above, just as the physician would be prohibited from referring patients to the hospital, the hospital would be prohibited from billing for any services that it furnishes to such patients.)

According to the Centers for Medicare & Medicaid Services (CMS), the Stark Law reflects Congress' concern that a physician with a financial stake in determining whether or where to refer a patient may be "unduly influenced by a profit motive," thereby undermining efficient utilization, patient choice, and competition among participants in federal health care programs.²² More specifically, CMS believes that:

- Physicians can "overutilize by ordering items and services for patients that, absent a profit motive, they would not have ordered,"²³
- A patient's choice "can be affected when physicians steer patients to less convenient, lower quality, or more expensive providers of health care, just because the physicians are sharing profits with, or receiving remuneration from, the providers,"²⁴ and
- Where referrals are "controlled by those sharing profits or receiving remuneration, the medical marketplace suffers since new competitors can no longer win business with superior quality, service, or price."²⁵

Where a physician has violated the referral prohibition and an entity has violated the billing prohibition, several sanctions may be imposed. First, an entity that collects payment for DHS performed pursuant to a prohibited referral must refund all collected amounts on a timely basis.²⁶ Second, any person "who presents or causes to be presented a bill or claim" for improperly referred DHS and "knows or should know" that the claim is for improperly referred DHS is subject to (1) a civil monetary penalty (CMP) of up to \$15,000 per service, (2) an assessment (in lieu of damages) of up to three times the amount claimed, and (3) exclusion from participation in any federal health care program.²⁷ Finally, any physician or entity that knowingly participates in a "scheme" to circumvent the Stark Law is subject to a CMP of up to \$100,000 and may be excluded from participation in federal health care programs.²⁸

Before turning to a discussion of how the Stark Law might be implicated by various ACO arrangements, several points are worth emphasizing.

Overbreadth of Law

The Stark Law's prohibitions are extremely broad. For example: (1) a physician has a "financial relationship" with any hospital with which the physician has a "compensation arrangement,"29 (2) a compensation arrangement includes "any arrangement" between a physician and hospital that "involves remuneration,"30 and (3) "remuneration" means "any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind."31 Thus, if a hospital provides a physician with anything of value, regardless of how small (e.g., note pads),³² the hospital and physician have a "financial relationship" and, in the absence of an exception, the physician may not refer Medicare patients to the hospital for DHS, and the hospital may not bill anyone for DHS furnished to such patients.

Proliferation of Exceptions

Because its prohibitions are so broad, the Stark Law is overinclusive, implicating thousands of common, everyday provider-physician arrangements, the vast majority of which do not offend any of the Stark Law's underlying policy objectives. For this reason, Congress and CMS have created some three-dozen separate exceptions to the Stark Law's prohibitions.

Complexity

In addition to the Stark Law's overbreadth, and the panoply of resulting exceptions, the Law can be difficult to navigate for a third reason: many of the Stark Law's elements and exceptions are complex, counterintuitive and, in some cases, have been defined, interpreted, redefined and reinterpreted on multiple occasions over the past two decades. Here are but two examples: the Stark Law definition of the word "referral" is more than 370 words long,³³ and the term "indirect compensation arrangement" was undefined by CMS until 1998,³⁴ was defined by CMS in 2001,³⁵ and was redefined by CMS in 2004,³⁶ 2007,³⁷ and 2008.³⁸

Strict Liability

To raise the compliance stakes still higher, the Stark Law is (generally speaking) a "strict liability" statute. That is, unlike one of the Stark Law's cousins the federal health care program anti-kickback law,³⁹ which is violated only if the defendant acts "knowingly and willfully" - the Stark Law may be violated even if the parties do not intend to violate the Law and are not aware that they are doing so. For example, assume that a physician and a hospital have a "financial relationship" because the hospital has given the physician some notepads and that this financial relationship does not fit into an exception. Under these circumstances, each and every time the physician refers a Medicare patient to the hospital for DHS, the Stark Law's referral prohibition may be violated; and each and every time the hospital bills Medicare (or anyone else) for DHS furnished to such patients, the Stark Law's billing prohibition may be violated - all regardless of whether the physician or the hospital intended to violate the Stark Law or were even aware that such violations were occurring.

Private Enforcement

All of the factors that make the Stark Law so challenging from a compliance standpoint probably would be manageable for the health care industry if the federal government had exclusive jurisdiction to enforce the Law. Unfortunately, this is not the case. Although the jurisprudence in this area is evolving, several courts have concluded that when a provider submits a claim for services that were furnished as a result of a referral that violated the Stark Law, that submission may constitute a "false claim" for purposes of the Federal Civil False Claims Act (FCA). The FCA, in turn, has a qui tam (or "whistleblower") provision, which allows private individuals and organizations to bring FCA actions in the name of (and on behalf of) the federal government.⁴⁰ If the whistleblower prevails, he or she is entitled to keep as much as 30 percent of the proceeds of the litigation (which may include treble damages and a fine of up to \$11,000 per claim), as well as reasonable expenses and attorneys' fees.⁴¹ With all of this background and context in mind, we turn now to whether and how the Stark Law might be implicated by ACO arrangements.

Potential Application to ACO Arrangements

As set forth above, determining whether an arrangement violates the Stark Law essentially is a three-step process.

- 1. **Referrals.** Does the arrangement involve a "physician" making a "referral" "to" an "entity" for the "furnishing" of "DHS" covered by Medicare?
- Financial Relationship. If so, does the physician (or one of his or her immediate family members) have a "financial relationship" with the entity furnishing DHS, either in the form of (1) a direct or indirect ownership interest or (2) a direct or indirect compensation arrangement?
- **3. Exceptions.** If so, does the arrangement qualify for protection under one or more of the Stark Law's exceptions?

Given the variety of physician, provider and payer arrangements that might fall into the ACO category, coupled with the complexity of the Stark Law which is widely (and accurately) viewed as among the most complicated of the federal health care fraud and abuse statutes — there is no "one-sizefits-all" Stark Law analysis of ACO arrangements. That being said, several observations can be made relating to each of the above questions and their potential application in the ACO context.

Referrals

Assuming that the ACO in question includes some combination of physicians and hospitals, it is likely that the participating physicians will have occasion to refer Medicare beneficiaries to the participating hospitals for the furnishing of inpatient and/or outpatient hospital services. In some cases, these beneficiaries may be enrolled in the ACO in question. In other cases, the beneficiaries may be patients of participating physicians but not ACO enrollees. In either event, their referral to a participating hospital may implicate the Stark Law. Moreover, in addition to inpatient and outpatient hospitals services, DHS include:

- Clinical laboratory services,
- Physical therapy services,
- Occupational therapy services,
- Outpatient speech-language pathology,
- Radiology services, including MRIs, computerized axial tomography (CAT) scans, PET scans, and ultrasound services,
- Radiation therapy services and supplies,
- Durable medical equipment (DME) and supplies,
- Parenteral and enteral nutrients, equipment and supplies,
- Prosthetics, orthotics, and prosthetic devices and supplies,
- Home health services, and
- Outpatient prescription drugs.

Thus, to the extent that entities furnishing any of these services participate in the ACO in question,

referrals of Medicare beneficiaries to such entities by participating physicians may violate the Stark Law.

Financial Relationship

If we assume that under the ACO arrangement in question, participating physicians will have occasion to refer Medicare patients to participating hospitals (and/or other participating DHS entities), the next question is this: will the ACO arrangement create any "financial relationships" between these physicians and these DHS entities? Unfortunately, there is no single (or simple) answer, other than, "it depends."

As a threshold matter, determining whether a "financial relationship" exists between a referring physician and a DHS entity is highly fact-specific and can be complex. This is particularly so where the potential financial relationship takes the form of a "compensation arrangement" (as opposed to an "ownership or investment interest"). As noted above, compensation arrangements may be "direct" or "indirect" and CMS' view (and interpretation) of "indirect" compensation arrangements has varied widely over the years.

Notwithstanding the above, the following safely can be said: if (1) the ACO arrangement in question provides for shared savings (or any other payments) to be provided to participating physicians, and (2) the source of this remuneration is a participating hospital - either because the hospital is the source of the funds in the first instance or because the hospital is exercising control over funds provided by a payer or other third-party - then the arrangement likely will create a "compensation arrangement" between the hospital and the physician for Stark Law purposes. Under these circumstances, the ACO would not be viable from a Stark Law standpoint unless this hospital-physician compensation arrangement meets the requirements of one or more Stark Law exceptions, is covered by an ACA waiver, or is the subject of a favorable CMS advisory opinion.

On the other hand, if (1) the source of the funds in question is not a participating hospital, but instead is a payer, and (2) the funds flow directly from the payer to the physician — without passing through (or otherwise being controlled or influenced by) a hospital (or other DHS provider) — then the arrangement may not create a compensation arrangement between the physician and any DHS entity. Under these circumstances (that is, in the absence of a financial relationship between the referring physician and any DHS provider), it would not be necessary to meet the requirements of any exception to the Stark Law, for example, in order to avoid liability thereunder.

In July 2008, CMS proposed a new Stark Law exception that would cover certain shared savings and similar arrangements ("July 2008 Proposed Rule"). (This proposed exception is addressed in detail below.) In discussing the need for such an exception, CMS touched on the financial relationship issue, largely confirming the provider/ payer dichotomy discussed above:

The provision of monetary or nonmonetary remuneration by a hospital to a physician through a gainsharing arrangement or other incentive payment or shared savings program would constitute a financial relationship with an entity for purposes of the physician selfreferral statute.

* * *

We observe that payer-based programs in which the performance measures are set by a wholly independent, arms-length party with a clear financial incentive to make [pay-forperformance] payments prudently may pose somewhat less risk than non-payer based programs, where there is no third-party payer that sets the performance measures and monitors compliance. We note further that payments made directly from a payer to a physician, at the payer's sole discretion, may not implicate the physician self-referral statute or other fraud and abuse statutes.⁴²

In sum, an ACO may be able to avoid implicating the Stark Law exposure altogether if it is structured in such a way that any remuneration that flows to physicians pursuant to the ACO's shared savings (or similar) arrangements does not come from (and is not controlled by) any hospital or other DHS entity. If this cannot be avoided, however, then the arrangement will need to meet the requirements of a Stark Law exception.

Exceptions

Although there are several Stark Law exceptions that are commonly employed where a hospital and physician have a compensation arrangement including the employment⁴³, personal services⁴⁴, fair market value⁴⁵, and indirect compensation arrangement exceptions⁴⁶ — none of these was designed with shared savings or similar programs in mind. As a result, it is rarely the case that one of these programs fits neatly into one of these exceptions. CMS recognized as much in the preamble to its July 2008 Proposed Rule:

The Medicare program and private industry stakeholders are increasingly exploring the benefits of various types of gainsharing, pay-for-performance (P4P), value-based purchasing, and similarly-styled programs that use economic incentives to foster high quality, cost-effective care. Many of these programs involve payments from hospitals to physicians. These payments potentially implicate the fraud and abuse laws, including the physician selfreferral statute. Existing exceptions to the physician self-referral statute, while useful, may not be sufficiently flexible to encourage a variety of non-abusive and beneficial gainsharing, P4P, and similar programs.⁴⁷

"For this reason," the agency continues, "we are proposing a new, targeted exception to the physician self-referral statute for such programs."⁴⁸ According to CMS, the "design of the new exception presents a particular challenge":

crafting an exception that offers broad flexibility for innovative, effective programs, while at the same time protecting the Medicare program and beneficiaries from abuses. In reviewing various programs and industry suggestions, we have been struck by the considerable variety and complexity of existing arrangements, and the likelihood of continued future innovation in the structure and method of these programs. This variety and complexity make it difficult to craft a "one-size-fits-all" set of conditions that are sufficiently "bright line" to facilitate compliance and enforceability, yet sufficiently flexible to permit innovation without undue risk of program or patient abuse. The variety and complexity of these programs make them potential vehicles for the unscrupulous to disguise payments for referrals or compromise quality of care for patients in the interest of maximizing revenues.49

In light of these various concerns and considerations, CMS decided to take a "cautious" approach, proposing a "relatively narrow" exception and conceding that it is "unlikely to cover as many arrangements as interested stakeholders would like."⁵⁰ Before turning to the exception's specific requirements, several preliminary points are worth emphasizing.

- First, the proposed exception, although narrow, is exceedingly detailed, consisting of 16 separate conditions, most of which (in turn) have multiple sub-conditions.
- Second, CMS has sought comments on virtually every element of the proposed rule and it is likely that any final rule will include substantial changes and modifications.
- Third, even if the proposed exception were both simple and set in stone, it is important to recall that the proposed exception is just that: proposed. Thus, an ACO could not, today, rely

on this exception for protection under the Stark Law.

With these caveats in mind, the proposed "Incentive Payment and Shared Savings Programs" exception ("Shared Savings Exception") provides that "[r]emuneration in the form of cash or cash equivalent payments, but not including nonmonetary remuneration, provided by a hospital to a physician on the hospital's medical staff or to a qualified physician organization" will not create a "financial relationship" for Stark Law purposes, provided the following 16 conditions are met.

- Purpose of Program. The "remuneration" at issue must be "provided as part of a documented incentive payment or shared savings program" — or "program" for purposes of this chapter — that is designed to achieve (1) the "improvement of quality of hospital patient care services through changes in physician clinical or administrative practices" or (2) "[a]ctual cost savings for the hospital resulting from the reduction of waste or changes in physician clinical or administrative practices, without an adverse effect on or diminution in the quality of hospital patient care services."
- 2. Performance Measures. The program must identify "patient care quality measures or cost saving measures" (collectively, "performance measures") that (1) use "an objective methodology, are verifiable, are supported by credible medical evidence, and are individually tracked," (2) are "reasonably related to the hospital's or comparable hospitals' practices and patient population," (3) "[w]ith respect to patient care quality measures, are listed in CMS' Specification Manual for National Hospital Quality Measures," and (4) are "monitored throughout the term of the arrangement to protect against inappropriate reductions or limitations in patient care services."

- 3. Performance Measure Baseline/Target Levels. The program must establish (1) "[b]aseline levels for the performance measures using the hospital's historical and clinical data," (2) "[t]arget levels for the performance measures that are developed by comparing historical data for the hospital's practices and patient population to national or regional data for comparable hospitals' practices and patient populations," and (3) "[t]hresholds above or below which no payments will accrue to physicians."
- 4. Participating Physician Pool. At least five physicians (the "participating physician pool") must "participate in each performance measure." Physicians participating in the program ("participating physicians") (1) "must be on the medical staff of the hospital at the commencement of the program," and (2) "may not be selected in a manner that takes into account the volume or value of referrals or other business generated between the parties." "A hospital may elect to make . . . [the] program available to physicians in a particular department or specialty, provided that the hospital offers the opportunity to participate in the . . . program to all physicians in the department or specialty on the same terms and conditions."
- 5. Independent Medical Review. The program must require "independent medical review of the program's impact on the quality of patient care services provided at the hospital and corrective action if the independent medical review indicates a diminution in the quality of hospital patient care services." This review "must be completed prior to the commencement" of the program "(with respect to the program's potential impact on the quality of patient care services provided at the hospital) and at least annually thereafter." For purposes of this

condition, "independent medical review" means "written review by an individual or organization that is (1) "[n]ot affiliated with the hospital, (2) "[n]ot affiliated with any participating physician or any physician organization to which any participating physician belongs," and (3) "[a] t the time of the review, not participating in any incentive payment or shared savings program at the hospital."

- 6. Selection of Supplies & Devices. Under the program: (1) "[p]hysicians must have access to the same selection of items, supplies or devices as was available at the hospital prior to the commencement of the program, and must not be restricted in their ability to make medically appropriate decisions for their patients, including, but not limited to, decisions about tests, treatments, procedures, services, supplies or discharge," (2) the "hospital may not make a payment to a participating physician or a qualified physician organization for the use of an item, supply or device if the physician or qualified physician organization has an ownership or investment interest in, or a compensation arrangement with, the manufacturer, distributor or group purchasing organization that arranges for the purchase of the item, supply or device," and (3) the "hospital may not limit the availability of new technology that is "linked through objective evidence to improved outcomes and is clinically appropriate for a particular patient" and "[m]eets the same federal regulatory standards as technology available under the incentive payment or shared savings program (for example, approval by the Food and Drug Administration and Medicare or Medicaid coverage decisions)."
- Patient Notice. The hospital must provide "effective prior written notice to patients affected by the incentive payment or shared savings program" that (1) "[i]dentifies the physicians participating in the program," (2) "[d]iscloses that participating physicians receive

payments for meeting targets for performance measures," and (3) "[d]escribes the performance measures in a manner reasonably designed to inform patients about the program."

- 8. Documentation of Arrangement and Shared Savings Formula. The arrangement must be "set out in writing," "signed by the parties," and "specif[y] the remuneration (or a formula for the remuneration) in detail sufficient to be independently verified, including a comprehensive description of the incentive payment or shared savings program in which the physician is participating, the applicable baseline measures, and the targets for performance measures to be achieved by the participating physician." To satisfy this requirement, "each specific performance measure and the resulting payment (or a formula for the resulting payment) to the participating physician or qualified physician organization must be clearly and separately identified."
- 9. Reasonableness of Arrangement. The performance measures provided for under the arrangement must "not involve the counseling or promotion of a business arrangement or other activity that violates any federal or State law" and, in the aggregate, must be "reasonable and necessary for the legitimate business purposes of the arrangement."
- **10. Term of Arrangement.** The term of the arrangement must be between one and three years.
- 11. Payment Limitations Double Dipping, Diminution in Care. "Payments must take into account previous payments made for performance measures already achieved to ensure that the participating physician or qualified physician organization does not receive payment related to patient care quality improvements or cost savings that were achieved during a prior period of the

arrangement." In addition, "[n]o payment may be made for the achievement of cost savings that results in a diminution in hospital patient care quality with respect to that performance measure."

- 12. Payment Limitations Duration, Amount. "For purposes of calculating the actual payments to the physician, cost savings [must be] measured by comparing the hospital's actual acquisition costs for the items and supplies or costs of providing the specified services that are subject to the shared savings program to the hospital's baseline costs for the same items, supplies or services during the [one]-year period immediately preceding the commencement of the program."
- **13. Distribution of Payments.** "The remuneration to be paid over the term of the arrangement (or the formula for the remuneration)" (1) must be "[s]et in advance," must not "vary during the term of the arrangement," and must not be "determined in a manner that takes into account the volume or value of referrals or other business generated between the parties," (2) must not be "based in whole or in part on a reduction in the length of stay for a particular patient or in the aggregate for the hospital," (3) must be "[d]istributed to the physicians in each participating physician pool or in each qualified physician organization if the qualified physician organization consists of at least five participating physicians on a per capita basis with respect to each performance measure," and (4) must be "[p]aid directly to participating physicians or qualified physician organizations."

14. Overutilization of Federal Program Services.

The "remuneration paid to a participating physician or qualified physician organization may not include any amount that takes into account the provision of a greater volume of federal health care patient procedures or services than the volume provided by the participating physician or qualified physician organization during the period of the same length immediately preceding the commencement of the program as that covered by the payment."

- 15. Documentation of Payments. The hospital must maintain "accurate and contemporaneous" documentation of the incentive payment or shared savings program and make such documentation available to [HHS] upon request," including, but not limited to, the following: (1) the "written agreement between the parties," (2) the "basis for the selection of the performance measures," (3) the "selection and qualifications of the individual or organization designated as the independent medical reviewer," (4) the "written findings of the independent medical reviewer," (5) the "[c]orrective actions taken by the hospital based on the written findings of the independent medical reviewer (or any other review indicating that corrective action was needed)," (6) the "amount and calculation of payments made under the incentive payment or shared savings program, including the hospital's projected and actual acquisition costs where relevant," (7) the "re-basing of performance measures," and (8) the "written notification provided to hospital patients."
- **16. Anti-Kickback Law.** The arrangement must not violate the federal health care program anti-kickback law or "any federal or state law or regulation governing billing or claims submission."

Two final notes. First, where the payment at issue is not coming from a hospital or other DHS entity, but instead is coming from an insurer, at least two existing Stark Law exceptions may be available to protect certain "downstream" referrals. Under the Stark Law's so-called "risk-sharing" exception, the Law's referral and billing prohibitions do not apply if the compensation arrangement at issue
consists of "compensation pursuant to a risksharing arrangement" - including, but not limited to, "withholds," "bonuses" and "risk pools" -"between" an "MCO or IPA and a physician for services provided" to "enrollees" of a "health plan," provided that the arrangement does "not violate the [Anti-Kickback Law], or any federal or state law or regulation governing billing or claims submission."51 In addition, the Law's so-called "pre-paid plans" exception protects referrals that involve Medicare beneficiaries who are enrolled in "pre-paid plans".52 Pursuant to this exception, the Stark Law's referral and billing prohibitions simply do not apply to services furnished to enrollees of any one of nine types of pre-paid plans, including (but not limited to) most Medicare managed care plans.53

Second, to the extent that pursuant to §3022 of the ACA, an ACO arrangement includes individuals enrolled in the Medicare fee-for-service program, §3022 specifically authorizes the U.S. Department of Health & Human Services to "waive" the application of the Stark Law to approved ACO arrangements. Thus, if a §3022 waiver is obtained by the ACO at issue, referrals involving beneficiaries who are enrolled in the ACO should not violate the Stark Law.

Conclusion

For all of the reasons set forth above, the Stark Law may pose obstacles to the formation and operations of ACOs, depending on the specific types of providers and arrangements at issue. In particular, ACO models that call for hospitals or other DHS providers to fund, or control the funding of, payments to physicians are likely to implicate the Stark Law. These obstacles should not be insurmountable, however. Where payments are made by non-DHS entities, for example, the Stark Law may not be implicated and/or several Stark Law exceptions may be available to protect patient referrals. Further, depending on how liberally HHS chooses to exercise its ACA waiver authority, such waivers could go a long way toward protecting additional patient referrals from the Stark Law's prohibitions.

6.3: FEDERAL HEALTH CARE PROGRAM ANTI-KICKBACK LAW

The federal health care program anti-kickback law ("Anti-Kickback Law") is an older cousin of the Stark Law. The Anti-Kickback Law is a broad criminal statute that prohibits one person from "knowingly and willfully" giving (or offering to give) "remuneration" to another if the payment is intended to "induce" the recipient to (1) "refer" an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under a federal health care program (i.e., a "covered item or service"); (2) "purchase," "order," or "lease" any covered item or service; (3) "arrange for" the purchase, order, or lease of any covered item or service; or (4) "recommend" the purchase, order, or lease of any covered item or service.⁵⁴ The Anti-Kickback Law also prohibits the solicitation or receipt of remuneration for any of these purposes.⁵⁵ "Remuneration" includes anything of value.⁵⁶ The term "inducement" has been interpreted to cover any act that is intended to influence a person's reason or judgment.⁵⁷ Some courts have held that as long as "one purpose" of the payment at issue is to induce referrals, the Anti-Kickback Law is implicated.⁵⁸ Under this one-purpose rule, an arrangement may implicate the Law (1) even if inducing referrals is not the primary purpose of the payment and (2) even where there are other, legitimate reasons for the arrangement. Courts have also recognized, however, that a party may hope or expect that a particular arrangement will result in referrals without necessarily triggering the one-purpose rule.59

Because the Anti-Kickback Law is so broad, it covers a variety of common and non-abusive arrangements. Recognizing this overbreadth, Congress and the U.S. Department of Health & Human Services Office of Inspector General (OIG) — the lead enforcement agency with respect to the Anti-Kickback Law — have established a large number of statutory exceptions and regulatory safe harbors (collectively, "safe harbors"). An arrangement that fits squarely into a safe harbor is immune from prosecution under the Anti-Kickback Law. The safe harbors tend to be very narrow, however, and the OIG takes the position that immunity is afforded only to those arrangements that "precisely meet" all of the conditions of a safe harbor. Material or substantial compliance is insufficient. Moreover, safe harbors do not exist for every type of arrangement that does (or may) implicate the Anti-Kickback Law.

Importantly, however, the fact that a particular arrangement does not fit within a safe harbor does not mean that the arrangement implicates (or violates) the Anti-Kickback Law. In other words, although there are certain types of remuneration that necessarily implicate the Anti-Kickback Law and, therefore, must be safe harbored in order to ensure immunity from prosecution, most remuneration that flows between and among health care entities does not fall into this category.

For example, most hospitals have a variety of arrangements pursuant to which they provide remuneration to physicians who are in a position to refer patients to the hospital. When a hospital hires a physician to serve as a medical director, for example, the hospital normally compensates the physician for his or her services. This compensation is, of course, "remuneration." Just as plainly, however, this remuneration does not necessarily implicate the Anti-Kickback Law. Indeed, such remuneration will implicate the Anti-Kickback Law only if it is intended not only to compensate the physician for his or her services, but also to induce the physician to refer patients to the hospital. If the compensation is not intended to induce patient referrals, then - whether the arrangement is safe harbored or not - the arrangement will not implicate the Anti-Kickback Law.

Furthermore, the OIG recognizes that there are many arrangements that do implicate the Anti-Kickback Law and are not covered by a safe harbor, but that nevertheless do not implicate any of the Law's principal policy objectives and, as such, do not pose a material risk of program abuse or warrant the imposition of sanctions. In a nutshell, the Law's principal policy objectives are to (1) prevent the overutilization of health care items and services and any concomitant increase in federal health care program costs, (2) promote patient freedom of choice, and (3) promote market competition.

Finally, because the Anti-Kickback Law is so broad and the protection offered by its safe harbors so limited, Congress created, and the OIG has implemented, an "advisory opinion" program. Pursuant to this program, individuals and organizations may submit proposed (but not hypothetical) arrangements to the OIG and request, in effect, a "case-specific" safe harbor. As of September 2010, the OIG had issued more than 200 advisory opinions. In the majority of these opinions, the requestor's proposed arrangement arguably implicated the Anti-Kickback Law but could not be safe harbored. More often than not, however, the OIG concluded that the arrangement (1) did not implicate the statute's principal policy objectives, (2) did not pose a material risk of program abuse, and (3) as such, would not be subject to sanctions. As the above description suggests, the Anti-Kickback Law is similar in many respects to the Stark Law, both in terms of its overarching policy objectives and general prohibitions. By the same token, there are material differences between the two laws, including the following:

- The Anti-Kickback Law is a criminal statute, whereas the Stark Law provides for civil and administrative sanctions.
- The Anti-Kickback Law has a "state of mind" (or scienter) requirement (i.e., in order to be convicted, a defendant must have acted "knowingly and willfully"). The Stark Law is

a "strict liability" statute (i.e., the Stark Law's referral and billing prohibitions may be violated even if the physician, provider, or supplier did not intend to violate them).

- The Anti-Kickback Law covers all federal health care programs (with the exception of the Federal Employee Health Benefits Program); the Stark Law's referral and billing prohibitions apply only to Medicare.
- The Anti-Kickback Law may be implicated by any type of arrangement involving any type of health care or non-health care organization; the Stark Law focuses on physicians and their financial relationships with certain types of entities (e.g., hospitals) that furnish certain types of services (i.e., DHS).

Potential Application to ACO Arrangements

Determining whether an arrangement violates the Anti-Kickback Law is essentially a four-step process.

- 1. Remuneration. Does the proposed arrangement provide for "remuneration" of any kind to flow from an individual or entity in a position to benefit from the referral of federal health care program patients or business (e.g., a hospital) to an individual or entity in a position to make such referrals (e.g., a physician)?
- 2. Implication. If so, will (or may) the remuneration implicate the Anti-Kickback Law? That is, is the remuneration intended to induce the recipient to engage in conduct (e.g., patient referrals) that is prohibited by the Anti-Kickback Law?
- 3. Safe Harbors. If the remuneration does or may implicate the Law, can the remuneration be protected by an Anti-Kickback Law safe harbor?
- **4. Risk Analysis.** If not, will the proposed arrangement pose a material risk of program abuse?

As was the case with the Stark Law, the Anti-Kickback Law is sufficiently complex, and the types of ACO arrangements are sufficiently varied, such that there is no "one-size-fits-all" Anti-Kickback Law analysis for such arrangements. Once again, however, several observations relating to each of the above questions, and their potential application in the ACO context, can be made.

1. Remuneration

As a threshold matter, under most (and perhaps all) ACO arrangements, "remuneration" — in the form of shared savings, incentive payments, and the like — will flow from payers and/or providers (among others) to providers and/or physicians (among others). Thus, there is little question that most ACO arrangements will involve the payment of "remuneration."

2. Inducement

The next – and probably most critical – question is this: will any of the payments be intended to induce, or in exchange for, the past or future referral of federal health care program patients or business? If the answer is "no," then the Anti-Kickback Law will not be implicated, the arrangement at issue will not need to be safe harbored, and the overall risk of the arrangement under the Law will be minimal (to non-existent). If the answer is "yes" - that is, if even one purpose of the arrangement is to induce the referral of federal health care program patients or business to a payer, provider or any other individual or entity participating in the ACO then the arrangement is unlikely to qualify for safe harbor protection and likely to pose a material risk of program abuse under the Anti-Kickback Law. Put somewhat differently, those who are developing and implementing ACOs need to take steps - while the ACO is being designed, while the underlying agreements are being negotiated, and while the ACO is in operation — to ensure (1) whether a physician (or any other individual or provider) is entitled to shared savings or other payments under the ACO, and (2) that the amount of such payments

is not contingent upon the volume or value of the recipient's referral of federal health care program patients or business to a participating plan or provider. Rather, such payments should be based exclusively on specific and objective quality of care, costs savings, and related performance measures.

It should be emphasized that the potential Anti-Kickback Law risk posed by ACO arrangements is not theoretical. In its advisory opinions on hospital-physician "gainsharing" arrangements (discussed further below), the OIG has repeatedly observed that "[l]ike any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that [gainsharing arrangements] could be used to disguise remuneration from [hospitals] to reward or induce referrals by [physicians]."60 These concerns will apply in equal, if not greater, measure to potentially more sweeping and complex ACO arrangements that involve even greater amounts of remuneration and, potentially, a larger and more complex set of payers, recipients and payment arrangements.

Finally, it should be noted that many of the conditions set forth in the Stark Law's proposed exception for "Incentive Payment and Shared Savings Programs" (discussed above) would, if implemented, help to ensure that the ACO arrangement at issue does not implicate the Anti-Kickback Law. Most notably, perhaps, pursuant to the proposed exception:

 Participating physicians cannot be "selected in a manner that takes into account the volume or value of referrals or other business generated between the parties" (although a hospital may elect to make the program available to physicians in a "particular department or specialty, provided that the hospital offers the opportunity to participate in the . . . program to all physicians in the department or specialty on the same terms and conditions").

- The remuneration to be paid under the arrangement cannot be "determined in a manner that takes into account the volume or value of referrals or other business generated between the parties."
- The remuneration paid to participating physicians cannot "include any amount that takes into account the provision of a greater volume of federal health care patient procedures or services than the volume provided by the participating physician or qualified physician organization during the period of the same length immediately preceding the commencement of the program as that covered by the payment."

3. Safe Harbors

Where an arrangement involves an exchange of remuneration between providers and referral sources, "best practices" are to safe harbor the arrangement if at all possible, even if there are no indicia of a quid pro quo between the parties. Simply put, if an arrangement fits squarely into an Anti-Kickback Law safe harbor, arguments about whether a particular fact is or is not evidence of an intent to induce referrals become moot.

As is the case with the Stark Law, there are several Anti-Kickback Law exceptions and safe harbors that are commonly employed where a hospital and physician have a compensation arrangement, including those covering certain employment⁶¹ and personal services⁶² arrangements. As under the Stark Law, however, none of these was designed with shared savings or similar programs in mind and, as a result, it is rarely the case that one of these programs fits neatly into one of these exceptions or safe harbors. Further, unlike CMS, the OIG has not promulgated any proposed safe harbor for ACO (or ACO-like) arrangements.

As under the Stark Law, however, there are certain managed care exceptions under the Anti-Kickback Law that may protect ACO arrangements that are considered "downstream" of an insurer. The socalled "shared risk"⁶³ and "health plan"⁶⁴ exceptions, for example, would fall into this category. Further, as discussed above, ACA specifically authorizes the U.S. Department of Health & Human Services to "waive" the application of the Anti-Kickback Law to approved ACO arrangements. Thus, to the extent such a §3022 waiver is obtained by the ACO at issue, referrals of participating beneficiaries should not violate the Anti-Kickback Law.

4. Risk Analysis

Because most ACO arrangements (1) will involve an exchange of remuneration, (2) this exchange will be between parties who are in a position to refer federal health care program business to one another, and (3) this remuneration may not be capable of safe harbor protection, whether and the extent to which a particular ACO arrangement poses a material risk of program abuse under the Anti-Kickback Law will require a careful "facts and circumstances" risk analysis.

The most important risk factor effectively relates back to the inducement question: that is, if there are any indicia that a purpose of the shared savings or other payments provided under the ACO are intended to induce future (or reward past) referrals of federal health care program patients or business, then the arrangement will pose potentially substantial risk under the Anti-Kickback Law.

Assuming no such quid pro quo exists, other risk factors — and associated safeguards — can be gleaned from two sources. First, because the Anti-Kickback and Stark Laws share the same fundamental objective — preventing the increase in federal health care program costs that can result from the overutilization of covered items and services — ACOs can reduce their overall risk under the Anti-Kickback Law by complying with CMS' proposed Stark Law Shared Savings Exception (detailed above) or any finalized version of this proposed Exception. Second, the OIG has issued a number of advisory opinions over the past several years addressing a variation on the ACO theme: hospital-physician "gainsharing" arrangements. These opinions address the types of concerns (and associated safeguards) that are likely to apply in the broader ACO context as well. For example, in 2008, the OIG opined on an arrangement between a hospital and five physician groups (four cardiology groups and a radiology group). In a nutshell, the arrangement at issue in OIG Advisory Opinion 08-21 was as follows:

- The hospital agreed to pay each group "a share of cost savings directly attributable to specific changes" in that particular group's cardiac catheterization procedures.
- Underlying the arrangement was a study of the historical practices of the groups with respect to such procedures performed at the hospital. The study identified a number of specific cost saving opportunities and made 27 recommendations falling into three categories:
 - Product standardization (e.g., standardizing the types of cardiac catheterization devices and supplies employed by the groups, based on both clinical and cost considerations);
 - "Use as needed" devices (e.g., limiting the use of certain vascular closure devices and cutting balloons to an "as needed" basis for coronary interventional and diagnostic procedures); and
 - Product substitutions (e.g., substituting, as appropriate, less costly contrast agents and anti-thrombotic medications for other products being used by the physicians).
- The arrangement included several safeguards against "inappropriate reductions in services."
 For example, physicians were required to make a "patient-by-patient determination of the most appropriate device or supply" and to ensure that the "availability of the full range of devices and

supplies" was not compromised by the product standardization, use as needed, or product substitution policies. In addition, "[t]o minimize the physicians' financial incentive to steer more costly patients to other hospitals," a committee monitored the "case severity, ages, and payers of the patient population treated under the [a]rrangement."

In analyzing the arrangement, the OIG noted that, on the one hand, "[p]roperly structured, arrangements that share cost savings can serve legitimate business and medical purposes" (i.e., "properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability"). On the other hand, the agency posited, "such arrangements can potentially influence physician judgment to the detriment of patient care."

Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Turning to the Anti-Kickback Law analysis specifically, the OIG noted that the arrangement "could encourage the physicians to admit federal health care program patients to the [h]ospital, since the physicians receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings." "In other words," the agency stated, "the more procedures a physician performs at the [h]ospital, the more money he or she is likely to receive under the [a]rrangement." In addition, the OIG stated, "[m]ultiple-year gainsharing arrangements raise a particular concern, in that they can inappropriately carry over earlier-accomplished savings across years, effectively accounting for them more than once." The "resulting unearned duplicate payments can amount to unlawful kickbacks from hospitals to physicians, if accompanied by illicit intent." Notwithstanding these concerns, however, the OIG concluded that the arrangement "poses a low risk of fraud or abuse under the [Anti-Kickback Law]" and, as a result, that the agency would not "impose sanctions in the particular circumstances presented here." The OIG's reasoning was as follows. First, the agency noted, the "circumstances and safeguards of the [a]rrangement reduced the likelihood that the [a]rrangement has been used to attract referring physicians or to increase referrals from existing physicians." Specifically:

- "[P]articipation in the [a]rrangement was limited to physicians already on the medical staff, thus limiting the likelihood that the [a]rrangement would attract other physicians."
- The "potential savings derived from procedures for federal health care program beneficiaries were capped based on the physicians' prior year's admissions of federal health care program beneficiaries."
- The "period for which payments have been calculated was limited to one year (and the [a]rrangement was rebased at the end of the first year)."
- The "overall amount of available cost savings payments over the entire two year term of the contract has been capped, reducing any incentive to switch facilities."
- "[A]dmissions were monitored for changes in severity, age, or payer."

In sum, "while the incentive to refer was not necessarily eliminated, it has been substantially reduced."

Second, the structure of the [a]rrangement "eliminated the risk that the [a]rrangement has been used to reward surgeons or other physicians who refer patients to the [g]roups or their physicians." That is, the groups: were the sole participants in the [a]rrangement and were composed entirely of cardiologists and interventional radiologists; no surgeons or other physicians are members of the [g]roups or will share in their profit distributions. Within the [g]roups, profits are distributed to members on a per capita basis, mitigating any incentive for an individual physician to generate disproportionate cost savings.

Third, the OIG noted, the "product standardization, limitation on use of devices and supplies, and product substitution each carried some increased liability risk for the physicians" and it "is not unreasonable for the physicians to receive compensation for the increased risk from the change in practice."

Moreover, the payments to be made represent portions of two years' worth of cost savings and are limited in amount (i.e., the rebasing and aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels).

In sum, the "payments under the [a]rrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to have implemented the twentyseven recommended actions, the specificity of the payment formula, and the cap on total remuneration to the [g]roups."

Conclusion

ACO arrangements are likely to involve the payment of remuneration between and among individuals and entities in a position to refer federal health care program business to one another. Further, many of these arrangements may not fit squarely within any Anti-Kickback Law exception or safe harbor. These arrangements will not implicate (or violate) the Anti-Kickback Law, however, provided that they are not intended — in whole or in part — to induce the referral of federal health care program business. In addition to ensuring the absence of any such quid pro quo, the implementation of a variety of safeguards — which have been identified by the OIG in similar contexts — can help to minimize any risks posed by ACO arrangements under the Anti-Kickback Law.

6.4: FEDERAL SERVICES REDUCTION CIVIL MONETARY PENALTY LAW

In addition to laws - such as the Stark and Anti-Kickback Laws – aimed at addressing the potential overutilization of covered items and services, certain federal health care laws are intended to address the opposite issue: the underutilization of such items and services. For example, the federal civil money penalty (CMP) laws provide that if a "hospital . . . knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided with respect to individuals" who are (1) entitled to Medicare or Medicaid benefits and (2) "under the direct care of the physician," then the hospital and physician are subject to a CMP of \$2,000 for each individual with respect to whom the payment is made.⁶⁵ For purposes of this publication, will refer to this as the "Services **Reduction CMP.**"

Potential Application to ACO Arrangements

Payments By Hospitals to Physicians

As a threshold matter, the Services Reduction CMP only applies to payments from hospitals to physicians. Thus, to the extent that shared savings or similar payments under an ACO are not being provided by a hospital (e.g., they are being furnished by a payer) or are not being paid to a physician (e.g., they are being furnished to any other provider or supplier), the Services Reduction CMP will not be implicated by the arrangement.

Reduce or Limit Services

If the payments are made by a "hospital" to a "physician," however, the CMP will be implicated if they serve as an inducement to "reduce or limit" the services provided to Medicare or Medicaid beneficiaries "under the direct care of the physician." The OIG has interpreted this element of the Services Reduction CMP quite broadly. For example, in 1999, the OIG issued a Special Advisory Bulletin entitled, "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries." As its title suggests, the Bulletin interprets the Services Reduction CMP in the context of so-called "gainsharing" arrangements. According to the Bulletin, and as discussed above, these arrangements typically involve a hospital giving "physicians a percentage share of any reduction in the hospital's costs for patient care attributable in part to the physicians' efforts." These arrangements, the OIG continued:

seek to align physician incentives with those of hospitals by offering physicians a share of the hospital's variable cost savings attributable to Medicare and Medicaid reimbursement. Since the institution of the Medicare Part A DRG system of hospital reimbursement and with the growth of managed care, hospitals have experienced significant financial pressures to reduce costs. However, because physicians are paid separately under Medicare Part B and Medicaid, physicians do not have the same incentive to save hospital costs. Gainsharing arrangements are designed to bridge this gap by offering physicians a portion of the hospital's cost savings in exchange for identifying and implementing cost saving strategies.

The OIG recognized that "hospitals have a legitimate interest in enlisting physicians in their efforts to eliminate unnecessary costs."

Savings that do not affect the quality of patient care may be generated in many ways, including substituting lower cost but equally effective medical supplies, items or devices; re-engineering hospital surgical and medical procedures; reducing utilization of medically unnecessary ancillary services; and reducing unnecessary lengths of stay. Achieving these savings may require substantial effort on the part of the participating physicians. Obviously, a reduction in health care costs that does not adversely affect the quality of the health care provided to patients is in the best interest of the nation's health care system.

"Nonetheless," the OIG concluded, "the plain language of [the CMP] prohibits tying the physicians' compensation for such services to reductions or limitations in items or services provided to patients under the physicians' clinical care." The OIG emphasized that the Services Reduction CMP "is very broad." For example, "[t] he payment need not be tied to an actual diminution in care, so long as the hospital knows that the payment may influence the physician to reduce or limit services to his or her patients." Further, "[t] here is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care." In short, "any hospital incentive plan that encourages physicians through payments to reduce or limit clinical services directly or indirectly violates the statute."

Since issuing the Bulletin in 1999, the OIG has addressed the Services Reduction CMP in connection with a number of advisory opinions. For example, in addition to considering the Anti-Kickback Law in Advisory Opinion 08-21 (summarized above), the OIG also analyzed the arrangement under the Services Reduction CMP. As a threshold matter, the OIG concluded that "all of the recommendations implicated the CMP." Simply put, with respect to the recommendations under the [a]rrangement regarding standardization of devices and supplies, limiting use of specific vascular closure devices and cutting balloons, and substitution of contrast agent[s] and antithrombotic medication, the [a]rrangement might induce physicians to reduce or limit the then-current medical practice at the [h]ospital. We recognize that the then-current medical practice may have involved care that exceeded the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

Risk Management

Unfortunately, the Services Reduction CMP (unlike the Stark and Anti-Kickback Laws) does not have any statutory exceptions or regulatory safe harbors. (Note once again, however, that the §3022 waiver authority under the ACA does extend to the Services Reduction CMP.) Thus, where an arrangement implicates the Services Reduction CMP, affected providers have three choices: (1) refrain from undertaking the arrangement at issue; (2) refrain from undertaking the arrangement until and unless a favorable advisory opinion is obtained from the OIG; or (3) undertake the arrangement subject to safeguards that are consistent with the guidance issued by the OIG over the past 10 years, thereby lowering – but not eliminating – the overall risk of the arrangement under the Services Reduction CMP.

Once again, many of the risk factors and safeguards associated with ACO-like arrangements can be gleaned from OIG advisory opinions. In Advisory Opinion 08-21, for example, the OIG concluded that notwithstanding the fact that the arrangement at issue implicated the Services Reduction CMP, it also incorporated "several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the [r]equestors."

- First, the "specific cost saving actions and resulting savings were clearly and separately identified." This "transparency" allows for "public scrutiny and individual physician accountability for any adverse effects" of the arrangement, "including any difference in treatment among patients based on non-clinical indicators." The "transparency of the incentives for specific actions and specific procedures also facilitates accountability through the medical-legal professional liability system."
- Second, there is "credible medical support for the position that implementation of the recommendations did not adversely affect patient care."
- Third, the amounts to be paid under the arrangement "have been calculated based on all procedures performed, regardless of the patients' insurance coverage, subject to the cap on payment for federal health care program procedures." In addition, the "procedures to which the [a]rrangement applied were not disproportionately performed on federal health care program beneficiaries." Further, "the cost savings have been calculated on the [h]ospital's actual out-of-pocket acquisition costs, not an accounting convention."
- Fourth, the arrangement "protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrued to the [g]roups." The requestors "have certified that these baseline measures were reasonably related to the [h] ospital's or comparable hospitals' practices and patient populations." In addition, these safeguards were "action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in cardiac catheterization practices."
- Fifth, the "product standardization portion of the [a]rrangement further protected against inappropriate reductions in services by ensuring that individual physicians still had available the same selection of devices and supplies after

implementation of the [a]rrangement as before." The arrangement "was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies."

- Sixth, the hospital and groups "provided written disclosures of their involvement in the [a]rrangement to patients whose care might have been affected by the [a]rrangement" and "provided patients an opportunity to review the cost savings recommendations prior to admission to the [h]ospital (or, where pre-admission consent was impracticable, prior to consenting to the procedure)." While "we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust."
- Seventh, the "financial incentives under the [a]rrangement were reasonably limited in duration and amount."
- Eighth, because "each of the [g]roups distributes profits to its members on a per capita basis, any incentive for an individual physician to generate disproportionate cost savings was mitigated."

In sum, the OIG noted, the arrangement is "markedly different from 'gainsharing' plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities." Rather, the arrangement "set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions." This transparency, in turn, "allowed an assessment of the likely effect of the [a]rrangement on quality of care and ensures that the identified actions are the cause of any savings." In short, "[g]iven the limited duration and scope of the [a]rrangement, the safeguards provided sufficient protections against patient and program abuse." "Other arrangements," however, "including those that are

longer in duration or more expansive in scope than the [a]rrangement, are likely to require additional or different safeguards."

6.5: FEDERAL TAX LAW

The development and implementation of ACOs raise two primary tax exemption questions. First, if a new "umbrella" entity is formed (as opposed to using a series of agreements among existing entities), can the entity qualify for tax-exempt status? Second, will any shared-savings or other payments between or among ACO participants be consistent with the tax-exempt status of any tax-exempt participants in the ACO?

Creation of New Entity

To determine whether a new entity can qualify for tax-exempt status, the relevant analysis is that applied by the IRS when considering exemption for integrated delivery systems (IDS), such as physician-hospital organizations (PHOs) and preferred provider organizations (PPOs). A typical PHO is formed as a nonprofit membership organization controlled equally by a tax-exempt charitable hospital and a medical group, an independent practice association, or individual physicians who practice at, or are affiliated with, the hospital. The PHO provides no health care services itself. Rather, it contracts with payors, on behalf of the hospital and physicians, for the provision of health care services in the community. Because the PHO's activities substantially serve the private interests of its member physicians, the PHO cannot avoid the proscription against more than incidental private benefit. Thus, tax exemption as a charitable organization is not available to the PHO. The IRS has taken a similarly dim view with respect to PPOs, which, in the IRS' view, are typically organized by the physician and hospital members primarily to attract additional patients and revenues to the participating providers and to increase the providers' market share.

It seems likely that the IRS would apply a similar analysis to ACOs and ACO entities seeking tax-exempt status. Thus, in order to qualify for exemption, the new entity would need to find a basis for exemption that is different from those rejected by the IRS for PHOs and PPOs. The malleability of the promotion of health rationale makes it a useful basis for exemption, particularly with ACOs' focus on improving quality of care. Another possibility would be the theory of "lessening the burdens of government." This was the rationale seized on by the IRS as a result of statutory language in the American Recovery and Reinvestment Act of 2009 (ARRA) to justify tax-exempt status for regional health information organizations. We note, however, that recently the IRS appears to be limiting the "lessening the burdens of government" rationale to exemptions for Regional Health Information organizations (RHIOs).

It should also be noted that the primary goals of the ACO - i.e., to improve guality and lower cost are favorable factors for exemption. The IRS has expressly identified these as favorable reasons for entering into joint ventures by exempt organizations. The ACO network is a joint venture since it involves multiple participants sharing risk and reward. Another possibility would be to create an ACO coordinating entity as a tax-exempt 501(c)(4) social welfare organization. This is a type of tax exempt organization that enjoys many of the same benefits of charitable status but has additional flexibility with regard to the IRS' community benefit standard and that has much greater flexibility with respect to lobbying and political campaign activity, should that become necessary.

Payment of Incentives

With respect to the second issue — whether any shared-savings or other payments between or among ACO participants will be consistent with the tax-exempt status of any tax-exempt participants in the ACO — the IRS is likely to analyze such payments in the same manner that it analyzes gainsharing and pay for performance (P4P) programs. With respect to gainsharing arrangements, for example, the IRS has ruled favorably where (1) the physician groups provided valuable services needed by the hospital, (2) the arrangements resulted in cost savings to the hospital, and (3) the allocation of the awards was capped to reflect fair market value, as determined by an independent third-party appraiser. Due to the "facts and circumstances" nature of the payments contemplated by ACOs, however, it may be advisable for tax exempt organizations to obtain a private letter ruling from the IRS confirming that participation in the ACO will not have an adverse affect on their status.

Conclusion

Although it may be difficult for an ACO to obtain tax exempt status, to the extent the ACO can be distinguished from many typical PHO and PPO models — with a focus on the ACO's primary purpose to lower costs and improve the health of the community — obtaining tax exempt status may be possible. Further, provided certain fair market value and other safeguards are implemented, hospitals and other organizations that participate in ACOs should be able to preserve their tax exempt status.

6.6: OTHER POTENTIAL LEGAL ISSUES

In addition to those discussed above, ACO arrangements — depending on their precise makeup and operation — may raise additional legal issues. For example:

 State Self-Referral, Anti-Kickback and Similar Fraud and Abuse Laws. Most states have one or more physician self-referral, antikickback and/or related fraud and abuse laws. In some cases, these state laws largely mirror their federal counterparts. In other cases, however, these laws can be narrower or broader than the Stark and Anti-Kickback Laws. In all events, the arrangements — and, in particular, the payment arrangements — underlying an ACO should be analyzed under both federal and state fraud and abuse laws.

- Civil False Claims Acts. Under the federal civil False Claims Act (FCA), a person who "knowingly" "presents" or "causes to be presented" a "false" or "fraudulent" "claim for payment" to the U.S. government is liable for a civil penalty of up to \$11,000 per claim, plus three times the amount of damages sustained by the government.⁶⁶ FCA actions may be brought by private "whistleblowers" who are entitled to up to 30 percent of any recovery. Increasingly, FCA actions are being brought on the ground that the claim at issue is "false" because it is for services that were furnished pursuant to a patient referral that violated the Stark Law or Anti-Kickback Law. This potential collateral risk needs to be considered when analyzing any proposed ACO arrangement. In addition, it should be noted that many states have their own false claims (or similar) statutes.
- Private Inurement/Private Benefit. In general, • a 501(c)(3) organization cannot be organized or operated for the benefit of private interests and the net earnings of a 501(c)(3) organization may not inure to the benefit of any private shareholder or individual. If one or more 501(c) (3) organizations is participating in an ACO, then — depending on the nature and formula for determining any shared savings or similar payments - these private inurement and/ or private benefit rules could be implicated. For example, to the extent that an ACO arrangement calls for a shared savings payment from a 501(c)(3) hospital to a physician group, and the payment exceeds fair market value, the arrangement could implicate the private inurement and/or private benefit rules.
- Government Managed Care Programs. Congress and CMS have created a complex web of statutes and regulations that govern the Medicare Part C – also known as Medicare Advantage (MA) – and similar programs. To the extent that patients participating in ACOs

include enrollees in such programs, these statutes and regulations could be implicated. For example, CMS' MA regulations provide for the imposition of sanctions on an MA organization that "[f]ails substantially to provide, to an MA enrollee, medically necessary services that the organization is required to provide . . . and that failure adversely affects (or is

substantially likely to adversely affect) the enrollee."67

- Corporate Practice of Medicine. Many states have what are commonly referred to as "corporate practice of medicine" (CPOM) laws. In general, these laws prohibit the practice of medicine or the employment of physicians by business corporations. Again, depending on (1) an ACO's corporate form (if any), (2) its underlying arrangements with physicians, and (3) its location, the ACO could implicate one or more COPM laws.
- State Insurance Laws. Bundled or capitated payments are a likely component of the ACO model. Some states require that health care providers assume financial risk in the provision of health care services to consumers, and that employer groups be regulated as health insurers. This can entail risk-based capital reserve requirements and other state law obligations, making it difficult for provider organizations (and ACO components) to enter into risk-sharing agreements.

CONCLUSION

The intent of this chapter is to identify areas of potential legal concern for an ACO, as well as how organizational and other choices may ameliorate concerns. Legal analysts are quick to stress how little is known about what existing laws might be altered in light of ACA or where exceptions may be granted by their enforcers. Not only does ACA explicitly give rulemakers authority to grant a number of exceptions and waivers to existing legal restrictions, but we further know from previous cases (e.g., Massachusetts) that other regulatory reforms are likely to follow in course from federal and state regulators in response to market demand. Furthermore, integration efforts across provider groups is not a recent phenomenon due to ACOs. Rather this has been a strategy used by health care organizations for many years in an attempt to better manage care delivery.

There is a burden on the Department of Health and Human Services, FTC, DOJ, state regulators and other rulemakers and enforcers to design and interpret regulations to ensure ACOs function effectively and are able to "ramp up" quickly. This will require an alignment of principles across these state and federal stakeholders. These principles must be conveyed to health care organizations as they strategize on the best ways to manage health care costs and quality. Along those lines, there will be a great deal of burden on ACOs to be clear and comprehensive when laying out their consolidation plans to justify how they will result in clinical improvement. Furthermore, they will need to be able to supply meaningful evidence (i.e., data) on the impact of these consolidation and clinical transformation efforts.

That said, while legal ambiguity may prompt a "wait and see" approach to aspects of ACO implementation among some health systems, most of these legal barriers can be avoided with proper legal counsel. For this reason, it is again worth stressing that any organization considering participation in an ACO should consider legal counsel a necessity. Being sure to build design elements in the context of both federal and state limitations will prevent costly revisions down the road and, ultimately, build sustainable business models to improve value across the system.

ENDNOTES

1. Good starting points are the FTC/DOJ Statements of Antitrust Policy in Health Care (the "Guidelines").

2. Whether a particular situation is likely to raise antitrust issues is a fact-based inquiry that requires the analysis of many variables. So, while we set forth general principles, whether a particular situation raises concerns necessarily requires a review of the facts associated with the particular conduct in question.

3. Section 1 of the Sherman Act, 15 U.S.C. § 1. The law applies to conduct involving two or more actors that are legally capable of conspiring. A single entity is legally incapable of conspiring. See, e.g., *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 755 (1984) ("Section 1").

4. The FTC and DOJ do not define what they consider to be a substantial withhold. However, in various Business Review Letters and Advisory Opinions, the government has approved withholds which are in the range of 15%- 20%. The withhold is usually coupled with already discounted fees. See, e.g., Advisory Opinion to George Q. Evans, July 5, 1994; Business Review Letter to Alan C. Nelson, M.D., July 23, 1999. A withhold of less than 15% might pass muster – it would all depend on the facts and on whether the withhold provided sufficient incentive for providers to modify their behavior and work more efficiently in an effort to receive the return of the withhold.

5. FTC /DOJ Statements of Antitrust Enforcement Policy in Health Care Statement 8, ("Health Care Statement 8)

6. There is no requirement that a clinically integrated network negotiate provider reimbursement agreements on behalf of the member providers. See discussion below regarding ways to mitigate market power issues.

7. ld.

8. ld.

- 9. See, e.g., Advisory Opinion Letter to Christi Braun, April 13, 2009.
- 10. Statement 9, Multiprovider Networks.
- 11. See Statement 8, Physician Network Joint Ventures.
- 12. Id.

13. See Brown Shoe Co. v. United States, 370 U.S. 294, 344 (1962); see also, Levine v. Central Florida Medical Affiliates, Inc., 72 F.3d 1538, 1551 (11th Cir.) 1996).

14. 425 U.S. 1, 17 (1976)

15. 425 U.S. at 17

16. 116 FTC 1526, 1527 (1993)

17. See Staff Advisory Letter to BJC Health System (November 9, 1999), in which the Bureau of Competition concluded that the resale of pharmaceuticals to a health system's employees is a resale for the health system's own use within the meaning of the NPIA. See also FTC Advisory Opinion to Bruce J. Toppin (January 7, 1998), in which the FTC stated that the NPIA protected a hospital's resale of drugs that it purchased at discounted prices to indigent cancer patients who used the hospital's Cancer Center; FTC Advisory Opinion to Robert M. Langer (December 20, 2001), in which the FTC stated that a hospital association's dispensation to its retired employees with vested retirement benefits meets the definition of "own use." Previously, the Supreme Court in Abbott Laboratories, see discussion *supra*, clearly held that dispensation by a hospital to its own employees meets the definition of "own use." The FTC found persuasive the hospital association's argument that benefit plans are necessary to attract and retain quality employees "for sufficient time for them to become eligible for retirement and pension benefits." The retention of such employees "directly promotes the hospitals' intended operation in the care of its patients" and, thus, dispensation of products purchased under NPIA is for the hospital's "own use." Id.

- 18. Abbott Labs, 425 U.S. at 14.
- 19. See, e.g., Jefferson Parish Hospital District No. 2 v. Hyde, 466 U.S. 2 (1984).
- 20. 42 United States Code (USC) §1395nn(a)(1)(A).
- 21. 42 USC §1395nn(a)(1)(B).
- 22. Stark II, Phase II Proposed Regulations (Preamble), 63 Federal Register (FR) 1659, 1662 (1998).
- 23. Stark II, Phase II Proposed Regulations (Preamble), 63 FR 1659, 1662 (1998).
- 24. Stark II, Phase II Proposed Regulations (Preamble), 63 FR 1659, 1662 (1998).
- 25. Stark II, Phase II Proposed Regulations (Preamble), 63 FR 1659, 1662 (1998).
- 26. 42 USC §1395nn(g)(2); 42 Code of Federal Regulations (CFR) §411.353(d).
- 27. 42 USC §1395nn(g)(3); 42 CFR §§1003.102(a)(5), 1003.102(b)(9), 1003.105.
- 28. 42 CFR §1395nn(g)(4); 42 CFR §1003.102(b)(10).
- 29. 42 USC §1395nn(a)(2)(B); 42 CFR §411.354(a)(1)(ii).
- 30. 42 USC §1395nn(h)(1)(A); 42 CFR §411.354(c).
- 31. 42 USC §1395nn(h)(1)(B); 42 CFR §411.351.
- 32. Stark II Proposed Regulations (Preamble), 63 FR 1659, 1699 (1998).
- 33. 42 CFR §411.351.
- 34. Stark II Proposed Regulations (Preamble), 63 FR 1659, 1705-1706 (1998).
- 35. Stark II, Phase I Regulations, 66 FR 856, 958-959 (2001), setting forth 42 CFR §411.354(c)(2).
- 36. Stark II, Phase II Regulations, 69 FR 16054, 16134 (2004), setting forth a revised 42 CFR §411.354(c)(2).
- 37. Stark II, Phase III Regulations, 72 FR 51012, 51087 (2007), setting forth a revised 42 CFR §411.354(c)(2).
- 38. 2008 Stark Regulations, 73 FR 48434 (2008), setting forth a revised 42 CFR §411.354(c)(2).
- 39. 42 USC §1320a-7b(b).
- 40. 31 USC §3730.
- 41. 31 USC §3730(d).

42. 73 Fed. Reg. 38502, 38549 (July 7, 2008). Under certain, narrow circumstances (e.g., where it owns and operates the providers that are furnishing the DHS at issue), a payer may constitute a "DHS entity." In such cases, a "financial relationship" between the payer and physicians could create Stark Law issues. In the vast majority of cases, however, payers are not considered DHS entities.

43. 42 C.F.R. § 411.357(c).
44. 42 C.F.R. § 411.357(d).
45. 42 C.F.R. § 411.357(l).
46. 42 C.F.R. § 411.357(p).
47. 73 Fed. Reg. 38502, 38548 (July 7, 2008).
48. 73 Fed. Reg. 38502, 38548 (July 7, 2008).
49. 73 Fed. Reg. 38502, 38548 (July 7, 2008).
50. 73 Fed. Reg. 38502, 38548 (July 7, 2008).
51. 42 C.F.R. §411.357(n).
52. 42 C.F.R. §411.355(c).

53. The Medicare Managed Care Plans include: (1) "[a]n HMO or a CMP in accordance with a contract with CMS under [§]1876 of the Act and part 417, subparts J through M of this chapter"; (2) "[a] health care prepayment plan in accordance with an agreement with CMS under [§]1833(a)(1)(A) of the Act and part 417, subpart U of this chapter"; (3) "[a]n organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project under [§]402(a) of the Social Security Amendments of 1967 (42 U.S.C. [§]1395b-1) or under [§]222(a) of the Social Security Amendments of 1972 (42 U.S.C. [§]1395b-1 note)"; (4) "[a] qualified HMO (within the meaning of [§]1310(d) of the Public Health Service Act)"; (5) "[a] coordinated care plan (within the meaning of [§]1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with CMS under [§]1857 of the Act and part 422 of this chapter"; (6) "[a] MCO contracting with a State under [§]1903(m) of the Act"; (7) "[a] prepaid inpatient health plan (PIHP) or prepaid ambulance health plan (PAHP) contracting with a State under part 438 of this chapter"; (8) "[a] health insuring organization (HIO) contracting with a State under part 438, subpart D of this chapter"; (8) "[a] nentity operating under a demonstration project under [§]1115(a), 1915(b), or 1932(a) of the Act."

54. 42 USC §1320a-7b(b)(2).

55. 42 USC §1320a-7b(b)(1). Where the anti-kickback statute has been violated, the government may proceed criminally or civilly. If the government proceeds criminally, a violation of the law is a felony punishable by up to five years' imprisonment and a fine of up to \$25,000. Id. §§1320a-7b(b)(1)-(2). If the government proceeds civilly, it may impose a civil monetary penalty of \$50,000 per violation and an assessment of not more than three times the total amount of "remuneration" involved, and it may exclude the defendant from participating in Federal health care programs. Id. §§1320a-7a(a)(7), 1320a-7(b)(7).

56. 56 Federal Register (FR) 35952, 35958 (July 29, 1991). Unlike the Stark Law, the anti-kickback statute does not have an exception for de minimis amounts and remuneration means anything of value, no matter how small.

57. Hanlester Network v. Shalala, 51 F.3d 1390, 1398 (9th Cir. 1995).

58. See, e.g., *United States v. Greber*, 760 F.2d 68 (3rd Cir. 1985), cert. denied, 474 U.S. 988 (1985); *United States v. Davis*, 132 F. 2d 1092 (5th circuit 1998); *United States v. Katz*, 871 F. 2d 105 (9th Cir. 1989).

59. Hanlester Network v. Shalala, 51 F.3d 1390, 1398 (9th Cir. 1995); United States v. McClatchey, 217 F.3d 823, 834.

60. See, e.g., Advisory Opinion 08-21 (November 25, 2008), at 14.

- 61. 42 C.F.R. § 1001.952(i).
- 62. 42 C.F.R. § 1001.952(d).
- 63. 42 C.F.R. § 1001.952(t).
- 64. 42 C.F.R. § 1001.952(m).
- 65. 42 U.S.C. §1320a-7a(b)(1).

66. Stark II, Phase II Regulations (Preamble), 69 FR 16054, 16957 (2004).

67. 42 C.F.R. § 422.752(a)(1).