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Transforming Health Care Through Accountable Care Organizations

A Critical Assessment

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I. INTRODUCTION

The health care industry is abuzz about accountable care organizations (ACOs). They are trumpeted as an answer to much of what ails our health care system and hold great promise as the vehicle that, short of rationing, may provide many of the answers both government and industry have been seeking in order to address the cost and variability of care issues in health care. According to proponents of ACOs, ACOs will transform our health care delivery and payment systems and will restrain health care cost increases while producing better health care outcomes.

ACOs are viewed as a way to address the perverse incentives created by our fee-for-service physician payment system that generally rewards the provision of more services, and not better or more efficient care. Properly structured, ACOs may be effective in reducing unnecessary diagnostic tests and procedures, dangerous drug interactions, and unnecessary drug treatments; facilitating access to needed care; and ensuring effective communication among all members of the patient's clinical team. This model is designed to result in not only cost savings to the system, but increased quality and patient satisfaction.

If successful, ACOs may achieve the "Triple Aim" of health care, as articulated by the Institute for Healthcare Improvement, the organization formerly led by Dr. Don Berwick, the new administrator of the Centers for Medicare & Medicaid Services (CMS):

- Improvement to the health of the population
- Enhancement to the patient experience of care (including quality, access, and reliability)
- Reduction, or at least control of, the per capita cost of care

While ACOs hold promise for each of these objectives, and while it seems axiomatic that better coordination of care through models such as ACOs would be a substantial improvement over our current fragmented care delivery arrangements, the jury is out on whether ACOs will achieve their potential. Our health care delivery system is not yet structured to promote ACOs or reward ACO participants for their efforts in providing more coordinated and cost-effective care.

If they are to be successful, ACOs will need to address effectively numerous business, financial, operational, technological, and legal challenges. These challenges are discussed in some detail below. Conversion to an ACO-based system would constitute a sea change in how care is currently delivered and reimbursed. The vast majority of providers would need to change significantly how they organize themselves and practice for ACOs to succeed. ACOs also need to understand how payors are approaching accountable care and what they intend to do, or not do, to support it, in order to understand the economic risks involved in the venture. But, with a commitment from the government, payors, and providers, and with careful and thoughtful ACO planning and structuring, it may be possible to overcome all these hurdles and transform our health system for the better in the process.

It is perhaps because of uncertainties about ACOs that the recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care Education and

Reconciliation Act of 2010 (collectively PPACA),[1] does not mandate utilization of ACOs. Rather, PPACA predominantly calls for introducing accountable/coordinated care models on a voluntary basis through pilot programs, demonstration projects, and other private initiatives that will provide an opportunity to study and assess the models. Those pilot programs and demonstration projects contemplate studying incremental changes in payment methodologies — principally shared savings and partial capitation arrangements, together with bundled and episodes-of-care payments for a limited number of specific medical conditions. This stepwise approach to payment reform is a practical necessity, since much of the health care system is not ready to accept and administer risk-based payments for a continuum of care across a variety of provider types. Certain proactive providers and health care systems are ahead of the curve and are already fairly far down the path toward being prepared to provide and be paid for accountable care.

While we believe that payment reform activities on the state, regional, and national levels are moving in the direction of ACOs, one real question is whether they will move fast enough to reward (or at least cover the cost of) ACO innovations by providers. Innovation carries the potential both for success and failure. Providers that get too far down the track too early may find themselves out in front of any return on investment, while providers that wait too long on the sidelines may give proactive providers a first-mover advantage to solving the many obstacles addressed in this white paper. The challenges for ACO development are very real and will vary by market — since all health care is, indeed, local. Providers that seek to implement ACOs will need to find solutions that work in their particular markets. As the following sections demonstrate, a number of knotty issues can be readily solved by proper structuring of the ACO from the outset. Indeed, the far greater risk to providers is that they seek to implement an ACO without being fully aware of these potential pitfalls and the ways to avoid them.

This white paper takes a critical but constructive look at ACOs and their role in national health reform and the health care marketplace.

The white paper is structured as follows:

Section II discusses how ACOs are addressed in PPACA. PPACA sets forth minimum requirements for organizations to qualify as ACOs for purposes of participating in the Medicare shared savings and partial capitation program. PPACA also authorizes pilot and demonstration projects to test accountable care arrangements.

Section III discusses organizational and structural options for ACOs. The ACO is a flexible organizational concept that may take a wide variety of legal forms.

Section IV identifies some of the most significant financial, payment, technological, and practical issues that providers will confront in moving toward ACO arrangements and away from fee-for-service payment models. As one might expect, in changing the fundamental nature of how health care is to be delivered and paid for, those issues may prove quite challenging for many health care organizations.

Section V summarizes the principal legal issues that ACOs face and that must be addressed for ACOs to accomplish their intended goals. In certain instances,

[1] Public Laws 111-148 and 111-152 (2010).

modifications in applicable law may be needed to accommodate ACO operations.

Section VI recommends actions that organizations should take now, proactively, to prepare to take advantage of ACO opportunities.

II. ACOs UNDER PPACA: STRUCTURE AND OPPORTUNITIES

PPACA is broad framework legislation that leaves much detail to be filled in by regulation. This is true for health reform in general and for ACOs in particular. What is currently known about ACOs is therefore only a starting point on what will almost certainly be an evolutionary journey.

PPACA defines and begins to experiment with ACOs, but does not institutionalize them or require their broad implementation. Rather, aside from a voluntary Medicare shared savings program, PPACA calls for pilot programs and demonstration projects to test ACOs and accountable care concepts. Through these programs and projects, CMS will study what it may take to make ACOs work and to see whether and how various providers and payors prove able to overcome the many obstacles to their success.

A. Medicare Shared Savings Program

PPACA requires the Secretary of the Department of Health and Human Services (the Secretary), by January 1, 2012, to establish a shared savings program utilizing ACOs.[2] The shared savings program is voluntary, in the sense that no provider is required to participate. The shared savings program is designed to (i) promote accountability for care to Medicare beneficiaries; (ii) coordinate the provision of services and items provided to Medicare beneficiaries under Medicare Parts A and B; and (iii) encourage investment in technology infrastructure and care processes necessary to provide high-quality and effective care. ACOs are the vehicle through which the shared savings program is to be implemented.

Any group of providers, practitioners, and/or suppliers of items and services covered under Medicare Parts A and B that meets criteria set by the Secretary may form an "eligible ACO";[3] however, PPACA specifically provides that physicians and nonphysician professionals in group practices or networks, hospitals, and their employed professionals, and joint ventures of hospitals and professionals may constitute an ACO.[4] While the governance of an ACO may take any number of forms, providers and physicians will play an important role in determining what care is medically necessary and appropriate. To qualify as an ACO, eligible providers must:

- Agree to be accountable for the quality and cost of care provided to Medicare fee-for-service beneficiaries assigned to the ACO
- Agree to participate in the shared savings program for at least three (3) years

[2] PPACA § 3022. PPACA amends Title XVIII of the Social Security Act by adding a new Section 1899 to Title XVIII.

[3] PPACA § 3022; Section 1899(b) of Title XVIII of the Social Security Act.

[4] PPACA provides that physicians described in Section 1861(r)(1) of Title XVIII and practitioners described in Section 1842(b)(18)(c)(i) of Title XVIII who may participate are referred to as "ACO professionals."

- Establish a formal legal structure having shared governance that allows the ACO to distribute shared savings payments to participating providers and suppliers[5]
- Include enough primary care physicians to care for the Medicare fee-for-service population assigned to the ACO and have a minimum of 5,000 such Medicare beneficiaries assigned to it
- Have a leadership and management structure that includes clinical and administrative systems
- Define processes (such as through telehealth, remote patient monitoring, and/or other technologies) to promote evidence-based medicine and patient centeredness, report on quality and cost measures, and coordinate care
- Demonstrate that it meets patient-centeredness criteria established by the Secretary, such as the use of patient and caregiver assessments or individualized care plans[6]

A provider is eligible to participate in an ACO shared savings program only if the provider is not participating in another shared savings program under Section 1115A[7] or under a home medical practice pilot program.

The Secretary is required to establish appropriate measures to assess the quality of care furnished by the ACO, such as measures of clinical processes and outcomes, patient or caregiver experiences of care, and utilization. The Secretary also must develop updated performance standards on a regular basis. In turn, ACOs must provide to the Secretary reports and performance data necessary to evaluate the ACO's performance and the quality of care it provides.

In the shared savings program, each independent provider or supplier participating in the ACO[8] will continue to submit its own claims and be paid on a fee-for-service basis for the services it provides. However, the ACO will be eligible to receive additional "shared savings" payments if the ACO (i) meets the Secretary's quality of care and performance standards and (ii) is able to provide services at a cost that is at least a specified percentage less than a "benchmark" set by the Secretary.

During the reconciliation process, PPACA was amended to give the Secretary authority to use alternative payment methods (other than the shared savings approach) designed to improve the quality and efficiency of providing Part A

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[5] The term "legal structure" is not defined. In the absence of any guidance from CMS to the contrary, it would appear that a contractual affiliation arrangement among physicians and institutional providers that otherwise satisfy ACO requirements should also be able to constitute a "legal structure" for ACO purposes.

[6] PPACA § 3022; Section 1899 of Title XVIII of the Social Security Act.

[7] Section 1115A is the new section establishing the Center for Medicare and Medicaid Innovation.

[8] If the ACO entity is itself a Medicare participating provider, then the ACO also would continue to be paid for its services (and for the services of its employed workforce and the services of contract providers that reassign benefits to the ACO in accordance with the Medicare reassignment rules).

and Part B Medicare services.[9] In particular, a shared savings program established under Section 3022 of PPACA may be based on a partial capitation model that would put the ACO at risk for some, but not all, Medicare services. For example, the program could pay the ACO a capitated payment to cover all services and items provided under Part B of Medicare or to cover only Part B physician services.[10] However, recognizing the complexity of such an arrangement, PPACA provides that the Secretary may limit such an alternative payment structure to ACOs that are already highly integrated systems of care that are capable of bearing risk.

Section IV.D.1 of the white paper describes the shared savings program in more detail.

B. Pilot Projects and Demonstration Programs

PPACA authorizes many pilot and demonstration programs that will test accountable care concepts. None of these programs will necessarily become permanent, nor is participation required in any of the programs.

1. Bundled Payment Pilot Program

PPACA requires the Secretary to establish by January 1, 2013, a five-year pilot program under which Medicare would pay a "bundled payment" to reimburse providers for essentially all health care services provided during a particular episode of care. Bundled payments for episodes of care put the providers participating in the delivery of the bundled services at financial risk for the cost of services included in the "bundle" and therefore create a potent incentive to coordinate and provide cost-effective care.

Section 3023 of PPACA, which provides for the bundled payment pilot program, does not explicitly reference ACOs. Any group of providers that meets the requirements for the pilot program (including an ACO that includes a hospital, physicians, a skilled nursing facility, a rehabilitation facility, and a home health agency) may participate in the pilot program.

This bundled payment pilot program is described in more detail in Section IV.D.2 below.

2. Other Pilot and Demonstration Programs

Other pilot and demonstration programs set forth in PPACA to test methods of achieving accountable and coordinated care include:

- A Medicaid pediatric accountable care organization demonstration project in which a state may allow pediatric medical providers that meet specified requirements to be recognized as an ACO for purposes of receiving incentive payments under Medicaid that are

[9] PPACA § 3022(i)(3); Section 1899(i) of Title XVIII of the Social Security Act.

[10] PPACA § 3022(i)(2); Section 1899(i)(2)(A) and (B) of Title XVIII of the Social Security Act.

calculated in the same way as the Medicare ACO provisions for shared savings programs[11]

- A demonstration project to evaluate integrated care around a hospitalization[12]
- A Medicaid global payment system demonstration project under which a state shall adjust the payments made to an eligible safety net hospital system or network from a fee-for-service payment structure to a global capitation payment model[13]
- A pilot program testing pay-for-performance programs for certain Medicare providers[14]
- A demonstration project for individual wellness programs[15]
- Continuation of a gain-sharing demonstration program[16]
- A demonstration program to integrate quality improvement and patient safety training into clinical education programs for health professionals[17]
- A demonstration program to test improvements to community health integration models in certain rural communities[18]
- An extension of the rural community hospital demonstration program[19]

Each of these programs has its own participation standards and application processes.

3. Center for Medicare and Medicaid Innovation

PPACA establishes the Center for Medicare and Medicaid Innovation (the CMMI).[20] The CMMI is charged with developing and testing innovative payment and delivery system initiatives. The CMMI's broad range of activities involves experimenting with a variety of reforms and programs designed to reduce the growth in health care costs and to improve quality

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[11] PPACA § 2706; Section 1899 of Title XIX of the Social Security Act.

[12] PPACA § 2704; Amendment to Title XIX of the Social Security Act.

[13] PPACA § 2705.

[14] PPACA § 10326; Amendment to Title XIX.

[15] PPACA § 4206; Section 330 of the Public Health Service Act.

[16] PPACA § 3027; Section 5007 of the Deficit Reduction Act of 2005.

[17] PPACA § 3508.

[18] PPACA § 3126; Section 123 of the Medicare Improvements for Patients and Providers Act of 2008.

[19] PPACA § 3123; Section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

[20] PPACA § 3021; Section 1115A of Title XIX of the Social Security Act.

outcomes through increasing coordinated and accountable care. It can be anticipated that the CMMI will support the development of other programs that may prove suitable for ACO participation. Interested ACOs should consider applying to CMMI for funding of innovative accountable care arrangements.

Nothing in PPACA requires ACOs to be or become the foundation of the health care delivery and payment systems of the future. PPACA does, however, showcase ACOs and highlights that they are worthy of careful study, evaluation, and analysis. Providers will face many obstacles and challenges in organizing and implementing ACOs that will need to be worked through before ACOs can become a cornerstone of our health care delivery system.

Those obstacles and challenges are detailed below following a discussion of legally compliant options for structuring ACOs.

III. STRUCTURAL OPTIONS FOR ACOS

A. The Variety of ACO Models

An ACO is a flexible concept from an organizational perspective. An ACO can take any legal form permitted by applicable state law. As noted above, any group of providers and suppliers of health care services, howsoever organized, has the potential to qualify to be an ACO — if the group can meet applicable ACO performance standards and assume responsibility for the overall cost, quality, and care of a defined population of patients. Existing entities may qualify as ACOs. ACOs and ACO participants may be:

- An integrated delivery system (IDS), with hospitals, physicians, and other providers under common control
- Providers affiliated through clinical and/or financial integration or a contracting network
- A large primary care physician practice or a multi-specialty physician practice
- A physician hospital organization (PHO) that is clinically and/or financially integrated
- A medical foundation
- A staff model HMO
- A contracted group of suppliers
- A joint venture of two or more of the aforementioned

A key feature of an ACO is shared governance and physician input in decision-making. Another is agreement among all participants to accept accountability and control either through ownership or, more loosely, through a contracted network. Any provider organization that is clinically or financially integrated and coordinates its participating providers for ACO purposes may qualify.

B. An IDS May Be Best Positioned to Become an ACO

As noted above, there is no specific legal, organizational structure that ACOs must adopt. Rather, any corporate, business or contractual arrangement has the potential to qualify as an ACO. Thus, ACO participants have the flexibility to design and innovate organizational arrangements that conform to local provider and market circumstances and local state laws.

An IDS is among those that are likely to be best positioned to become an ACO. This form of organization includes both physicians and hospitals and covers a fair range of services in the continuum of care to manage the health care of ACO patients. Additionally, these organizations tend to have the capital, human resources, and administrative infrastructure needed to manage health care utilization and expense. Typically, providers within an IDS also are financially and clinically integrated, which provides the IDS with certain legal advantages in pursuing ACO goals.

For example, a financially or clinically integrated IDS is best situated to negotiate with all payors on behalf of participating providers without engaging in illegal price-fixing in violation of the antitrust laws. An IDS also can require

that all participating providers that are employed by the IDS to make appropriate referrals within the IDS network, to stem leakage to more expensive sites of service — a distinct advantage in managing utilization and cost of care — without violating the Anti-Kickback Statute (AKS) prohibition against paying for referrals or the Stark Law prohibition on self-referrals.

For these reasons, an IDS is more likely to be better equipped to manage or coordinate the care provided by its participants and to have the resources to assume the financial risk of managing the health care of a population of patients than would less-integrated provider organizations and organizations that do not include health care facilities at their core.

C. Other Potential ACOs

That an IDS is or may be among those well positioned to serve as an ACO is not to say that other provider organizations will not succeed as ACOs. Clinically integrated providers in other types of provider organizations (e.g., certain PHOs) may have many of the same strengths as an IDS. But, for any organization or group to function successfully as an ACO, it will need access to critical resources, including necessary capital, human, and other resources for this purpose (e.g., executive skills, medical management talent, clinical protocols, clinical decision support tools, quality and utilization management processes, credentialing, and peer review processes), and the information technology to support these functions. This may be expensive, and there is no assurance that any of these costs will be covered by any particular payor. Thus, the financial risk of developing the ACO infrastructure, and the potential risk of loss or gain from ACO operations, will fall squarely on the ACO provider organization (or its participants).

Which provider organizations have the resources to make such investments and take such economic risks? One answer is that it may be those provider organizations that can (or can more readily) access the debt and equity markets to raise necessary capital. Tax-exempt provider organizations cannot access the equity markets. So, among tax-exempt providers, the more likely ACO candidates are IDSs, health systems, strong community hospitals, and larger health care facilities that can issue tax-exempt (or taxable) bonds or that can fund the ACO out of operations. It would be a stretch for most medical groups, IPAs, or PHOs to fund a project like an ACO out of operating revenue. Nor do these organizations typically have the operating margins or creditworthiness to qualify for sizable loans on either a taxable or tax-exempt debt basis. Moreover, it is also not clear that the ACO would itself have any debt capacity independent of its sponsoring organization(s) or providers. So, among nonprofit or tax-exempt players, IDSs, health systems, strong community hospitals, and larger health care facilities may prove to be the better ACO candidates.

For-profit health systems that have access to the public and private equity markets are also among potential ACO candidates. Their access to the equity markets may provide these for-profit players with the necessary resources for successful ACO development.

For other for-profit provider organizations, like medical groups and practitioner organizations, another source of equity capital for ACO formation may be the participating providers themselves. Physicians, however, historically have been

unwilling to make significant personal investment in managed care IPAs or other similar entities and tend to be averse to personally guaranteeing the debt of such entities. It is therefore left to be seen whether physicians will perceive there to be a sufficient strategic imperative to invest in ACO formation — whether they feel compelled to capitalize ACOs for fear of otherwise being shut out of the market (or a significant portion of the market) or being relegated to the role of a minor vendor to someone else's ACO.

The jury is also out on whether the financial and business models for ACOs will project a sufficient rate of return on investment (ROI) to attract physicians or other investors. In the short run, the ability to generate a sufficient ROI will be directly related to the ability of the ACO to achieve substantial quality improvements and reductions in overall health care costs. In addition, the ACO will require capable management to monitor and control expenses in relation to revenues.

If there is a fair ROI to be earned, then we also may witness the emergence of a venture capital or private equity market to fund the development, growth and consolidation of ACOs and ACO-type entities and to position some of them ultimately to go public. Recently, private equity companies have been attracted to acquire certain hospitals, perhaps with this as a goal. Entrepreneurial providers and health care executives may want to explore these avenues of equity funding for ACOs.

IV. ACO Challenges: Financial and Practical

There are many business, financial, technological, infrastructure, operational, and legal challenges that ACOs will need to address and overcome in order to succeed. Some of the most vexing issues are explored in this section.

A. Multiple Payors Providing Inconsistent Incentives

The payor market, like the provider market, is relatively fragmented. There are hundreds of different health insurers and health care payment programs in the United States. Each has its own reimbursement policies, payment methodologies, and rates. There is no assurance that any particular payor will adopt the same method as any other payor for paying or incentivizing an ACO. Nor is there any assurance that an ACO will have sufficient market power to dictate or influence payment methodologies or product design by health insurers and other third-party payors. It is therefore likely, for the foreseeable future, that ACOs will have to contend simultaneously with multiple payors and multiple payment methodologies. Some payors may continue to pay the ACO on a fee-for-service basis, some may pay on a pay-for-quality/performance basis, some may pay on a shared savings basis, some may pay on a bundled payment or episode-of-care basis, some may pay on a partial or full capitation basis, and some may pay on a percentage of premium basis. In short, unless there are sufficient payors in the particular market that are willing to reward provider organizations for achieving ACO goals, there may not be an adequate incentive for provider organizations to make the capital and human resource investments and operational changes necessary to organize themselves into ACOs for the purpose of controlling utilization and costs and improving quality of care.

For example, if Medicare is the only payor that rewards ACOs on a shared savings or global capitation basis, and if Medicare is only 20 percent of the provider organization's business, then it may make no sense to have the "tail wag the dog" — there may be an insufficient critical mass and alignment of incentives to warrant the provider organization's investing in systems to administer shared savings or capitated payments and transforming itself into an ACO. With such a payor mix, incentives to manage utilization and cost may be overwhelmed by fee-for-service incentives to provide more services. For many provider organizations, it is administratively difficult simultaneously to administer effectively a managed care program for one cohort of patients and a fee-for-service system for another cohort of patients. As providers know, even small differences in payor payment processes and policies (e.g., eligibility verification, prior authorization, or payment policy) can require entirely different provider work flow processes and can add significantly to the administrative burden and cost of delivering health care. This may distract and detract from the ACO's primary mission of reorganizing providers to improve the way patient care is delivered. Moreover, there is currently no assurance that any payor will make transitional payments to support a provider organization in building ACO infrastructure or capacity. If a critical mass of payors is not aligned in recognizing and paying their fair share for the development and operations of the ACO's administrative infrastructure, then the provider organization may not be able to afford to become an ACO.

For these reasons, if ACOs are to flourish, there may be a need for broader-based payment reform. There would need to be a critical mass of payors willing to structure payments on a fairly uniform basis to meet the twin ACO goals of rewarding quality improvement and cost-efficient care. As discussed below, antitrust laws may constrain the ability of private payors to coordinate their products in this manner, in the absence of authorizing legislation or a legislative mandate.

B. Allocating the Dollars

Regardless of the methodology by which the ACO is paid, the ACO will need to determine how much of its revenue will be used to support administration of the ACO, how much will be reserved to fund capital improvements and growth, how much will be paid to its participating providers, how payments will be allocated among participating providers, and how much risk will be assumed by participating providers. This is true whether payments to the ACO are on a fee-for-service, aggregate pay-for-quality, shared savings, bundled payment, episode-of-care, or partial or global capitation basis. While the ACO may not have the market power to dictate the payment methodologies of its payors, it may have a fair amount of flexibility to dictate the method by which it will pay its participating providers.

For example, if the ACO is itself a Medicare participating provider (such as an IDS) and is paid by a payor on a fee-for-service basis for its employed physicians, the ACO could merely pass the fee-for-service payments through to participating physicians and take a percentage off the top to support ACO administration. Alternatively, though, the ACO could decide to redistribute ACO payments in furtherance of ACO quality and efficiency improvement goals. For example, the ACO could withhold 20 percent of all fee-for-service payments and make the withhold pool available to only those participating physicians who meet specified individual and aggregate quality standards and/or cost-savings targets (subject to the legal constraints discussed in Section V below). This would transmute fee-for-service payments from payors into risk-based payments to providers to reward desirable clinical behaviors and to disincentivize undesirable ones. Alternatively, the ACO could pool its fee-for-service payments for payors and transform them into internal shared savings, case rates, capitation, or other payment arrangements with participating providers.

These internal ACO decisions about payment methodologies and allocations will ultimately be made by the governing board of the ACO or a compensation or other committee that is delegated authority by the board to make such decisions. Independent benchmarks and appraisals may be important to establish the fair allocation of payments. An independent appraisal may be advisable to ensure fair market payments if the ACO is a tax-exempt entity or if payments will be made to independent contractor providers that are in a position to refer.

Given the key role of the ACO's governing board and committees in allocating compensation, governance of the ACO is and will be critically important to ACO participating providers. The structure and composition of the ACO board (and its decision-making committees), and the process for nominating and electing those decision-makers, are and will be vital to the legitimacy, credibility, integrity, and fairness of financial allocation decisions for all concerned. ACO

governance will need to strike the right balance among the very disparate economic interests of all the ACO participants — which may include a broad spectrum of providers, such as primary care physicians, specialists, hospital-based physicians, midlevel practitioners, other clinicians, ASCs, imaging centers, laboratories, hospitals, nursing homes, rehabilitation facilities, hospices, home health agencies, suppliers, and other health care providers. Developing fair financial arrangements that are acceptable to all these constituents and that are adjusted to remain so over time, requires a delicate balancing of interests by trusted leaders who are prudent stewards of the ACO. IDSs that employ or corporately control the various participants should have a much easier time developing and administering such payment methodologies than would a contracted network with which the ACO must periodically renegotiate financial arrangements at arm's length.

C. Infrastructure Needs

In large part, the success of an ACO will be a function of its ability to coordinate the care provided and to hold participating providers accountable for the cost and outcomes of care they provide. A common clinical, management, and information technology infrastructure will be important to support clinical integration, utilization and quality management, and care coordination.

Ongoing monitoring of the care through information technology and administrative infrastructure will be important to meet an ACO's goals. An electronic health record (EHR) that includes the capability for timely monitoring of care being delivered, and is available to all the ACO participants, is generally viewed as being critical to coordinating care and managing its cost. Timely access to such clinical and utilization information is key to keeping participating providers informed about the consequences of their care decisions, addressing noncompliance with the ACO's clinical protocols and policies, and taking corrective action when appropriate.

The cost of implementing an enterprise-wide EHR for those organizations that have not already done so may be great. Other information technology infrastructure costs that best practice ACOs may incur — for clinical decision support, provider credentialing, utilization management, cost accounting, quality reporting, provider and payor contracting, interoperability, encryption, and IT service and support for their provider networks — may be beyond the financial reach of many provider organizations. With additional human resource costs added in to support ACO functions, ACO infrastructure costs may indeed be prohibitive for many. Without transitional payment assistance from payors, and without a real prospect for a reasonable return on these considerable investments, few provider organizations may be able to afford the financial risk of converting to an ACO model.

D. ACO Payment Methodology Issues

1. Shared Savings

Shared savings arrangements may provide a logical transition step for ACOs evolving from fee-for-service payment systems toward full risk-based payments. This is because shared savings programs provide the potential for upside reward (from shared cost savings and pay-for-performance

bonuses) without the downside risk of exceeding a preset cost or utilization budget. In this manner, shared savings arrangements "hedge" the ACO's financial risk while providing incentives for improved quality and efficiency.[21]

Generally, under shared savings arrangements, the ACO assumes responsibility for the total care of a defined population of patients in exchange for an annual amount that the parties project the payor would otherwise pay for those patients on a fee-for-service basis. The ACO has the potential for additional payments if (i) the ACO meets applicable quality performance standards and/or (ii) if costs are reduced by a specified percentage below an applicable cost-savings benchmark that is pegged to the projected trend in fee-for-service costs for that patient population. Per-member per-month/year payments for individual patients also may be adjusted for demographic characteristics such as age, sex, and/or health condition.

For example, under the Medicare shared savings program, if the ACO meets applicable quality and cost-savings standards, payments shall continue to be made to providers and suppliers participating in an ACO under the original Medicare fee-for-service program in the same manner as they would otherwise be made, except that the participating ACO is [also] eligible to receive payment for shared savings.[22]

To be eligible for shared savings payments, the estimated average per capita Medicare expenditures for the Medicare fee-for-service beneficiaries for Parts A and B services for the beneficiaries assigned to the ACO, adjusted for beneficiary characteristics (e.g., age, sex, severity adjusted), must be below the applicable benchmark specified by CMS. The benchmark is to be set by CMS using the most recent available three (3) years of per-beneficiary expenditures for Medicare services furnished to the Medicare beneficiaries assigned to the ACO, and the benchmark is to be updated by the absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program. The ACO is then permitted to retain a percentage, to be determined by CMS, of the difference between the average per capita Medicare expenditures for those beneficiaries and the benchmark.[23]

To qualify for shared savings payments under the Medicare shared savings program, the ACO must submit data to CMS in a form and manner specified by the Secretary on quality measures determined by the Secretary, so that CMS can evaluate the quality of care furnished by the ACO. Such data may include PQRI standards and care transitions across care settings, including hospital discharge planning and post-hospital

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[21] The "Alternative Quality Care" contract of Blue Cross Blue Shield of Massachusetts and the Medicare shared savings program included in Section 3022 of PPACA are examples of shared savings programs.

[22] PPACA § 3022; Section 1899(d)(1)(B)(i) of Title XVIII of the Social Security Act.

[23] PPACA § 3022; Section 1899(d)(2) of Title XVIII of the Social Security Act.

discharge follow-up by ACO professionals.[24] CMS will seek to incentivize continuous quality improvement by specifying higher standards and/or new measures over time. Only if both (1) the applicable quality standards are met and (2) cost savings below the applicable percentage under the applicable benchmark are achieved can a participating ACO qualify for the additional shared savings amount.

Some of the key issues and challenges associated with such a shared savings arrangement are listed below.

- What services are ACO providers capable of providing?
- What services are covered, and what services are excluded?
- How will the ACO contract for out-of network services and manage out-of-network costs?
- What payments will be made directly to the ACO, and/or what payments will be made directly by payors to participating providers?
- How will the annual per-member amount be determined?
- What data (and what quality of the data) will be used to determine the per-member amounts?
- What trend factor will be applied?
- Will per-member payments be adjusted for age, sex, medical condition, and/or severity?
- Will payments be adjusted for changes in member health status over time, and if so, how?
- What will the applicable quality standards be?
- How will quality standards be set and revised over time?
- How and by whom will compliance with quality standards be tracked and measured?
- How does the ACO educate participating providers about applicable quality standards and incentivize them to meet those standards?
- How will the cost savings be determined and measured?
- What is the benchmark or percentage of savings below which cost savings will be shared, and how will it be determined?
- What percentage or amount of cost savings will the ACO be eligible to keep?
- Do the benchmarks get rebased (lowered) once savings are achieved, or do the cost savings continue to be shared with the ACO from year to year (or for a period of years)?
- What administrative infrastructure is needed to track and measure compliance with quality standards and cost savings?
- What safeguards will be needed to ensure that participating providers do not stint on care?

[24] PPACA § 3022; Section 1899(b)(3)(B), (C) and (D) of Title XVIII of the Social Security Act.

- Will the carrot of the shared savings payment be sufficient relative to fee-for-service payments to transform provider behavior?

Most of these questions cannot currently be answered by most provider organizations. This suggests that forming and operating an ACO, particularly from scratch, will be a complicated piece of business and that there may currently be inadequate information available by which to assess the economic feasibility and likelihood of success of such an ACO.

2. Bundled Payments and Episodes of Care

Medicare and some commercial insurers are experimenting with episodes of care, case rates, or bundled hospital-physician payments for specific cases, procedures, or services. This payment methodology carries greater economic risk for an ACO than does a shared savings arrangement. It may also create a greater potential upside opportunity if the ACO is appropriately structured to reap the rewards of the bundled rate methodology. Under a bundled payment arrangement, the ACO accepts the downside risk that the cost for providing the full package of services, across multiple providers and provider types, required to treat the patient during the episode of care will exceed the bundled payment. To the extent an ACO includes participating providers that span the continuum of services necessary to provide complete care for a patient with a particular medical condition, and the ACO has sufficient control or management of its participating providers, the ACO may be positioned to consider assuming the risk and potential reward from accepting bundled payments for an episode of care.[25]

An ACO that includes a hospital, a physician group, a skilled nursing facility, and a home health agency can qualify for the Medicare pilot program on payment bundling established by Section 3023 of PPACA.[26] That program is based on payments for episodes of care for inpatient hospital services. The purpose of the pilot is to promote "integrated care during an episode of care ... during a hospitalization in order to improve coordination, quality, and efficiency of health care services ... ."[27]

Under this payment program, CMS will select up to ten (10) medical conditions for which it will determine episode-of-care payment amounts, based in part on those conditions CMS finds most amenable to bundling across a spectrum of care, given historic practice patterns. For purposes of the pilot project, a hospital "episode of care" is defined as the period that includes (i) the three (3) days prior to inpatient admission for the patient, (ii) the hospital length of stay, and (iii) thirty (30) days following discharge from the hospital. Included within the payment bundle for the episode of

[25] For example, one large managed care company is piloting a case rate program for oncology where it is paying oncologists a specified amount in advance based on the patient's diagnosis, stage of cancer, and an applicable treatment protocol. That becomes the complete budget for treating that stage of the patient's cancer, including all physician, drug, outpatient, and inpatient services.

[26] PPACA § 3023; Section 1866D(c)(2)(A) of Title XVIII of the Social Security Act.

[27] PPACA § 3023; Section 1866D(a)(1) of Title XVIII of the Social Security Act.

care will be all care rendered during the applicable episode of care, including (i) acute care inpatient services; (ii) physician services, whether delivered in or outside of the acute hospital setting; (iii) outpatient hospital services, including emergency department services; (iv) post-acute care services, including home health care, skilled nursing, inpatient rehabilitation and long-term hospital services; and (v) other services that CMS deems appropriate.

Other bundled services may include care coordination, medication reconciliation, discharge planning, transitional care, and other patient-centered activities. Payments for episodes of care under the pilot program include CMS-set payment bundles and/or payment rates based on bids from entities, such as ACOs. Payments, however, must be set in a manner that does not result in spending more for the episode of care than Medicare would otherwise have spent in the absence of the bundling program.

CMS will establish quality measures for ACOs and other entities participating in the pilot bundling program. Data on the quality measures will be required to be submitted by participating entities through use of a qualified electronic health record. Based on the data submitted, CMS will evaluate and determine whether the program results in improving and not reducing the quality of patient care while reducing Medicare spending.

Some of the key issues under a bundled payment arrangement for an episode of care include the following:

- What services are conducive to being paid on an episode-of-care bundled payment basis?
- What is the range of services included in the episode of care?
- How are patients with chronic issues to be handled?
- Can ACO-participating providers provide all the bundled services?
- Are all ACO-participating providers committed and incentivized by a payment system to work within a bundled payment?
- How will the ACO control or manage the care of its participating providers?
- How does the ACO ensure that the patient will follow up with ACO providers and remain in-network throughout the episode of care?
- What happens if the patient experiences another medical condition or injury during the episode-of-care period?
- How is the bundled payment rate set?
- What are the data (and adequacy and quality of data) on which the bundled rate is determined?
- The same issues surrounding quality standards identified above for shared savings arrangements will also be present.
- How does the ACO pay its participants?
- How do you keep the ACO from cherry-picking healthy patients and shunning those with multiple and serious health issues?
- How is the cost of care during the episode of care determined and measured?

- What administrative infrastructure is needed to track and measure compliance with quality standards and cost of care?
- What safeguards are needed to ensure that participating providers do not stint on care during the bundled episode?

Payment bundling for episodes of care would put the ACO at financial risk and would incentivize the efficient provision of care for the specific episode of care. It would also promote collaboration among ACO participating providers involved in treating the patient during the episode of care. Bundled payments, however, do not fully address the perverse volume incentive in fee-for-service systems, since the payment bundle alone provides no incentive for providers to avoid episodes of care in the first place. Moreover, to date, there has been limited experience with designing and administering episodes of care. There is, therefore, some significant unknown implementation risk associated with accepting bundled payments for episodes of care.

Again, the issues associated with bundled payments and episodes of care are complicated and will need to be addressed in the CMS pilot program before this payment methodology is ready for prime time.

3. Capitation Payments

Unlike episode-of-care payments, partial or global capitation payments hold the potential to eliminate the perverse volume-based incentives of fee-for-service payments. Global payment methodologies involve setting a cost/utilization budget for health care services and an associated monthly/annual payment amount to compensate the ACO for all or a specified portion of care to be provided to a defined patient population over a defined period (e.g., a contract month or year). The monthly or annual capitation payment is generally based on an actuarial assessment of future economic risk of medical loss based on historic cost experience for patients with different demographic characteristics (e.g., age, sex, health condition and severity, geography, and/or socioeconomic status). Capitation payments are intended to reflect the expected costs of covered health care services for a particular population of patients. To protect ACOs from assuming insurance risk (as opposed to provider risk), global payments are generally risk adjusted so that they reflect the underlying health condition and probability of illness or injury among the particular cohort of patients. Global payments are also adjusted to reflect patient co-payments and deductibles, with lower capitation payments for products with higher consumer out-of-pocket costs (and associated disincentives to obtain health care).

Medicare Advantage and Medicaid managed care programs currently pay providers on a global or primary care capitation basis. In certain states, provider organizations that accept partial or global capitation risk are required to obtain a form of insurance license to be a risk-bearing entity or to meet specified financial solvency and capital reserve requirements. Commercial HMOs also historically have paid forms of ACOs, such as integrated provider organizations, PHOs, IPAs, or primary care groups, on a capitated basis.

Some of the key issues under a global capitation arrangement include the

following:[28]

- What services are covered, and what services are excluded (e.g., vision, dental, mental health, orphan drugs, specialty pediatric surgical services) from the global payment?
- What is the spectrum of services that the ACO provides and costs that it can control?
- How will the ACO contract for out-of network services and manage out-of-network costs?
- How are outlier costs defined and handled?
- On what data are the global payments based, and what is the quality and adequacy of the data?
- What stop-loss levels and risk corridors will apply, and what level of reinsurance is available at commercially reasonable rates?
- What risk will be passed on to providers individually and as a unit or subgroup, in the form of withholds and bonuses?
- What patient incentives will apply, in terms of co-pays, deductibles, tiered network incentives, preferred provider discounts, etc.?
- What number and composition of patients will yield actuarially sound risk?
- What risk adjusters will apply, and how accurate are they?
- How will individual provider participants be paid?
- How will the global payments be adjusted over time to account for changes in the demographic characteristics and health status of the patient population?
- Are payments adjusted for eligibility and fraudulent identity risks?
- How will the ACO manage incurred-but-not-reported (IBNR) cost risk?
- Who determines medical necessity, and how is it determined?
- Will there be preauthorization of services, and if so, for what services and by whom?
- What access and network adequacy standards will apply?
- What are the applicable quality standards?
- The same issues relating to quality standards as described above for shared savings and bundled payment arrangements will also be present.
- How is the cost of care determined and measured?
- What administrative infrastructure is needed to track and measure compliance with quality, utilization and cost standards?
- What safeguards are needed to ensure that participating providers do not stint on care to profit on the global payment?

[28] As discussed below, in Section V.C.1, ACOs will need to determine if they can accept capitation without being duly licensed or registered under relevant insurance laws.

- How are cherry-picking of patients and avoidance of the sicker patients to be controlled?

There has not been significant global capitation in the health care marketplace since the managed care backlash of the late 1990s. Only a few states, including California, New York, and Massachusetts, continue to have provider organizations that are at full risk for a significant percentage of patients. Global capitation thus would represent a sea change in payment methodology for most health care providers and payors. To be able to assume global capitation risk requires a substantial investment in medical management infrastructure for those organizations that do not already have this capability. The globally capitated ACO will also need to develop and implement clinical protocols for cost-effective care across a broad spectrum of medical conditions and specialties, to educate providers in the use of those protocols, to monitor provider compliance with protocols, and to take timely and effective action to reduce noncompliance when it occurs. It may also need to have available clinical decision support tools to assist providers in complying with approved protocols in real time at the point of care.

To be able to assume capitation risk, an ACO will also need the tools and systems to monitor and manage costs, utilization, and risk through prior authorization, as well as concurrent and retrospective review of the medical necessity of services. These are functions that are performed today to a greater extent by insurers than by provider organizations. This suggests that ACOs may need to make significant investment upfront in technology and administrative infrastructure to coordinate patient care across multiple provider settings and to manage the cost, utilization, and quality of health care services in those settings. Additionally, there will be upfront and continuing "insurance-related" compliance burdens and costs arising from state insurance/managed care laws in certain states, including registration and reporting requirements. As noted above, in the absence of front-loaded or transitional payments from third-party payors to fund this effort, it is not clear whether many provider organizations will have the financial means to become successful ACOs in a global or partially capitated payment system.

E. Adequacy of Payment

Payments to ACOs, whether under shared savings, bundled payment, episode-of-care, or partial or global capitation payment methodologies, need to be adequate to cover the reasonable costs of the ACO and its participating providers, including medically necessary costs of care and reasonable administrative costs of the ACO. And payments allocated by ACOs to their participating providers must be adequate to cover the participating provider's reasonable costs of providing medically necessary care. If the amount of payment is too low, the provider may be confronted with the dilemma of either being financially unable to deliver appropriate care or being driven toward (or into) insolvency. This may seem obvious, but the issue of payment adequacy can be complicated and vexing.

Payment adequacy is complicated because each provider, and each different provider type, incurs different costs. Wage, land, and facility costs vary by region. Facility, equipment, supply, pharmaceutical, and staffing costs vary by provider. Costs vary by size and market power of the provider, with stronger

organizations able to negotiate for discounts, rebates, and lower unit costs. Costs vary by patient acuity, by demographics and socioeconomic status, and by provider resource utilization. Certain organizations have unique costs, like the IME/GME, research, and academic costs of teaching hospitals. Costs vary by provider based on their disparate strategic, growth, marketing, and human resource development plans. Further, payments must be adequate to fund capital depreciation and replacement of equipment; recruitment of physicians and personnel; free care and bad debt litigation and unforeseen circumstances (such as outlier cases); and some degree of innovation, inefficiency, and community benefits. Costs also change for providers over time, due to inflation, new technologies, new pharmaceuticals, new legal mandates, new clinical standards, and new operational best practices. Costs for hospitals are different than costs for clinics, physician offices, or home health care agencies, even when they are providing precisely the same service. So, what is adequate payment for one reasonably efficient provider in one setting may be wholly inadequate for another reasonably efficient provider in a different geography or of a different provider type in the same geographic region, even when providing exactly the same service. It is this complexity that both the payments to the ACO and from the ACO to its participating providers must address in a fair and equitable manner.

To compound the payment adequacy problem, prices charged by health care providers and the rates they are able to negotiate may bear little or no relationship to the provider's costs. This is because some providers may have the ability to negotiate higher rates due to the provider's size, prestige, quality in one or more critical areas, or sole community provider status. This means that some providers have historically benefited from disproportionately high payment rates, while others have suffered from disproportionately lower rates. These market power and rate disparities are not magically resolved by organizing participating providers through an ACO. Rather, forming an ACO may simply convert the market power disparity from being an external pricing issue (in relation to payors) to being an internal one (in relation to participating providers).

Further compounding the payment adequacy issue is the problem of below-cost payments by certain payors, most notably the Medicaid programs. Many Medicaid programs pay only about 60 percent or less of the cost of care for their beneficiaries, with state-to-state variation. This means that other payors need to cross-subsidize those below-cost rates through higher payments. The net effect is that payments by payors do not correlate with reasonably efficient costs of providers. Rather the ratio of payments to costs probably varies significantly from service to service, from payor to payor and from provider to provider.

Moreover, if payors anticipate cost savings from a new payment methodology, the payor may try to estimate such cost savings upfront in the form of reduced payments to the ACO or may deny rate increases over time on the supposition that savings will be realized, obviating the necessity for normal inflation increases. However, if the expected savings are not realized, then the ACO and its participating providers may not be financially able to fully meet their care obligations. This, in turn, may result in stinting on care or financial difficulties for ACO providers.

F. Responsible Risk Sharing

Shared savings, bundled payment, episode-of-care, and partial or global capitated payment arrangements are designed to hold providers (or provider organizations) accountable for health care costs and outcomes for defined populations of patients. However, certain risks are not within the control or influence of providers. For example, insurance risk — that is, the risk of occurrence of illness or injury — is generally a random risk that providers cannot control (except to the extent that the illness or injury is the result of a preventable medical error). It would seem self-evident that providers cannot control and thus should not be financially at risk for gunshot-wound cases that end up in an emergency department. In negotiating risk-based payment arrangements, ACOs should seek to avoid assuming cost and utilization risks such as these or should address these risks through insurance or reinsurance. After all, that is the very purpose of insurance — to cover insurance-related risks. That is not the proper province of provider payments.

Another risk that providers may not want to accept (or fully accept) under risk-based payment arrangements is the risk of patient behavior. Even the best providers cannot always change or positively influence the lifestyle choices of their patients. A physician can advise a patient to give up smoking, abuse of alcohol or drugs, or overeating, and may inform the patient fully and exquisitely well about all the associated health risks, but the patient may nonetheless persist in his or her bad habits. Patients may be intractably noncompliant, even if they are financially incented to change their unhealthy ways. These patient-controlled risks can become economic risks to ACOs under risk-based payment arrangements, unless the ACO can identify and exclude these costs and risks from their payment contracts. Currently, there is limited system capability to identify, isolate, and exclude these costs and risks.

Theoretically, lifestyle risks that are within patient control could be addressed by targeted patient co-pays and deductibles — to put the financial risk of intentional unhealthy behavior on the patients who engage in those behaviors. This is principally an issue of health insurance product design. But few health insurance companies have evolved their products in this direction for a host of complicated socioeconomic and political reasons. This makes it difficult to hold consumers financially responsible for their own behavior within the context of our current health care delivery and payment system. The absence of consumer financial responsibility for their lifestyle choices shifts a significant portion of that risk to provider organizations such as ACOs, unless they are alert to the issue and negotiate to more appropriately allocate those costs and risks among insurers and patients.

V. CHALLENGES: LEGAL ISSUES

The complex world of financial relationships between physicians and hospitals, and among ACO providers, however the ACO is structured, will present a variety of legal issues under existing laws. The laws implicated include the AKS laws, physician self-referral laws, the federal Civil Monetary Penalty (CMP) law, antitrust laws, insurance laws, and tax-exemption laws. There are also state laws governing the practice of medicine that may impact formation of ACOs. In this section, we will discuss each of these sets of laws and their application to ACOs.

A. Anti-Kickback, Physician Self-Referral, and Civil Monetary Penalty Law

1. Overview of Current Regulatory System

Several existing health care laws are designed to regulate fraud, waste, and abuse in our health care delivery and payment systems. In the fee-for-service market in which our health system has operated, three principal laws regulate financial relationships between and among providers: the Ethics in Physician Self-Referral Law (known as the Stark Law),[29] the federal AKS,[30] and the CMP Law.[31] (We refer to the Stark Law, the AKS, and the CMP Law collectively as Fraud and Abuse Laws.)

In the current, predominantly fee-for-service health care payment system, the regulatory scheme under the Stark Law and AKS is predominantly focused on prohibiting payments that reward additional referrals. Fee-for-service payments that reward more care create an incentive to provide and bill for marginal and potentially unnecessary services. Additional goals of the Fraud and Abuse Laws are to insulate medical decisions from financial considerations, avoid cherry-picking of healthy patients and steering of sicker patients to other hospitals, prohibit payments in exchange for patient referrals, and avoid unfair competition. Because of the prospective payment system for hospitals under the Medicare program, the CMP Law was enacted to limit hospitals from improperly taking advantage of that system by paying physicians to reduce or limit services provided to federal health program beneficiaries under their care. Any such stinting on care could improperly improve the profit margin earned by hospitals on their fixed prospective payments from Medicare.

The new payment models described above in this white paper, which move from fee-for-service medicine to other payment models that promote accountable care, will present different regulatory risks. Existing laws present certain risks as the newer payment models seek to reach their goals of better outcomes and more efficient care delivery while protecting against fraud and abuse. Lewis Morris, the Chief Counsel to the Office of Inspector General of Health and Human Services (OIG), recently stated:

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[29] 42 U.S.C. § 1395nn.

[30] 42 U.S.C. § 1320a-7b(b).

[31] 42 U.S.C. § 1320a-7a(b)(1).

> As these new models develop in the health care market, the existing fraud and abuse laws will remain important fraud-fighting tools. However, some new arrangements may require new approaches to combating fraud, waste, and abuse. Moreover, depending on their design and operation, some new arrangements may pose different risks that will need to be addressed. These risks could include, for example, stinting on care, discrimination against sicker patients, misreporting quality and performance data, and gaming of payment windows to "double bill" for otherwise bundled services. Further, industry stakeholders have raised concerns that existing fraud and abuse laws designed to restrain the influence of money on medical decision-making may complicate or impede certain reforms because the fraud and abuse laws generally restrict economic ties between parties in a position to generate Federal health care program business for each other.[32]

For this reason, PPACA authorizes the Secretary of HHS to waive application of the Fraud and Abuse Laws to carry out each of the Medicare shared savings program and the bundled payment pilot program.[33] However, no such waiver is currently available for similar state fraud and abuse laws.

After a brief description of the three principal Fraud and Abuse Laws, we examine the particular requirements of these laws that will present challenges for ACOs to reach their intended goals of improved coordination, quality and efficiency of health care.

a. The AKS

The federal AKS makes it a criminal felony, knowingly and willfully, to offer, pay, solicit, or receive any remuneration to induce or reward referrals for, or the purchase, lease or order of, any item or service reimbursable by a federal health care payment program.[34]

As may be relevant to various financial relationships among or between ACO providers or participants, the AKS contains statutory exceptions. One is for payments by an employer to an employee for employment in the provision of covered items.[35] Another exception is for certain risk-sharing arrangements — that is, remuneration between

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[32] June 15, 2010, Testimony of Lewis Morris to the Subcommittees on Health and Oversight of the House of Representatives Committee on Ways and Means.

[33] See PPACA §§ 3022(f) and 3023(d).

[34] Improper remuneration includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The AKS is an intent-based statute. It has been interpreted to mean that there is a violation if any purpose of the remuneration is to pay for referral of any patient for any Medicare or Medicaid covered item or service. *See United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.) cert. denied, 474 U.S. 988 (1985).

[35] 42 U.S.C. § 1320a-7b(3)(B).

an organization and an individual or entity providing items or services if the remuneration is pursuant to a written agreement that, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services which the individual or entity is obligated to provide.[36]

Furthermore, the AKS authorizes the Secretary to adopt safe harbor regulations that, if all the conditions to a safe harbor are met, permits certain business arrangements that would otherwise potentially violate the AKS. As may be relevant to ACOs, there are safe harbor regulations for investment interests, personal services and management contracts, employment, and reduced cost-sharing amounts or premiums or price reductions offered by or to health plans.[37]

b. Stark Law

The Stark Law provides significant civil penalties for financial relationships between a physician or a physician's family member and an entity if the physician refers patients for specified designated health services (DHS) covered by Medicare to the entity, unless there is an exception authorizing the financial relationship.[38] The Stark Law is a strict liability statute that does not require any showing of intent; if there is a financial relationship directly or indirectly with a physician not subject to an exception and there is a physician referral of DHS, there is a violation.

The Stark Law exceptions, as relevant to ACOs, include exceptions for bona fide employment relationships, personal service relationships, risk-sharing arrangements, and indirect compensation arrangements.[39]

c. CMP Law

The CMP Law creates significant civil penalties for a **hospital** that 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 entitled to Medicare Part A or B benefits and are under the direct care of a physician. The payment must come directly or indirectly from a hospital to a physician for the CMP Law to be implicated. The CMP Law is an intent-based statute.

The OIG has indicated that while reductions in health care costs that do not adversely affect the quality of health care provided are in the best interests of our nation's health care delivery, the "plain language" of the CMP Law prohibits a hospital payment to a physician tied to

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[36] 42 U.S.C. § 1320a-7b(3)(F).

[37] See 42 C.F.R. §§ 1001.952(a), (d), (i), (k) and (l).

[38] See 42 U.S.C. § 1395nn.

[39] See 42 C.F.R. §§ 411.357(c), (d), (n) and (p).

reducing or limiting any government-funded services to patients under the physician's clinical care.[40]

PPACA, perhaps to address this particular issue, included an amendment to the CMP Law to exclude remuneration that "promotes access to care and poses a low risk of harm to patients and Federal health care programs ... ."[41] This amendment may be interpreted to permit appropriately structured shared savings programs between hospitals and physicians.

2. Application of Fraud and Abuse Laws to Different Payment Methods

The payment methodologies discussed in Section IV (i.e., shared savings programs, bundled payments, and global or partial capitation) that are likely to be available to ACOs raise a variety of issues under the Fraud and Abuse Laws. ACO payment arrangements will need to be structured carefully to avoid or significantly reduce these legal risks.

a. Shared Savings Programs

The Medicare shared savings program continues fee-for-service payments to ACO participants, but with the potential for additional payments based on cost savings. The continuation of fee-for-service payments means the general regulatory scheme of the AKS and the Stark Law, which is designed to control overutilization, will remain important regulatory constraints. The addition of the shared savings (or gainsharing) bonus payments presents a different set of issues that may also implicate the Fraud and Abuse Laws.

i. The AKS and the CMP Law

The sharing of cost savings under shared savings programs has been addressed to some extent by CMS and the OIG in their review of gainsharing arrangements. Shared savings programs and gainsharing programs are different names for somewhat similar programs. Both involve sharing savings or gains among participants, who are thereby jointly incentivized to achieve the results that generate the savings or gains to be shared. CMS and the OIG have, through a number of advisory opinions under the AKS and the CMP Law,[42] identified the issues and concerns they have with the gainsharing aspect of shared savings programs under the current legal framework.

The OIG first addressed gainsharing arrangements in a Special

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[40] HHS OIG, Special Advisory Bulletin, "Gainsharing Arrangements and CMP for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries," (July 1999).

[41] PPACA § 6402(d)(2)(B); Section 1128A of the Social Security Act.

[42] The AKS and the CMP Law are intent-based laws. Accordingly, CMS and the OIG have more flexibility to approve gainsharing arrangements through advisory opinions on those laws than they have in regard to the strict liability Stark Law.

Advisory Bulletin issued in July of 1999.[43] In that Special Advisory Bulletin, the OIG indicated that while appropriately structured gainsharing arrangements may offer significant benefits where there is no adverse impact on the quality of care received by patients, [the CMP Law] clearly prohibits such arrangements. Moreover, regulatory relief from the CMP prohibition will require statutory authorization.

The PPACA amendment to the CMP Law permitting remuneration that promotes access to care and poses a low risk of harm to patients may well indicate a congressional intent to statutorily authorize certain gainsharing/shared savings programs that adequately protect against harm to patients. The amendment gives ACOs protection for engaging in shared savings programs that contain safeguards (such as those described below) protecting against stinting on care. It can be anticipated that CMS/OIG will clarify the intent of this language in forthcoming bulletins or advisory opinions.

Moreover, notwithstanding the initial Special Advisory Bulletin, over time the OIG has issued numerous advisory opinions approving various forms of gainsharing arrangements.[44] In the advisory opinions, OIG has found that the gainsharing proposals implicate the CMP Law and the AKS. But the OIG has indicated there is a pathway to approval when certain safeguards are present. These opinions have approved substitution of less expensive items of medical equipment of equivalent clinical quality (e.g., less expensive stents or implants), payments for not opening sterile supply trays and kits until they are needed, and process improvements that result in demonstrable cost savings without compromising quality of care. CMS and the OIG, however, have made clear that the CMP Law does not permit a hospital to share with physicians generalized cost savings (e.g., beating the cost budget) or to reward reductions in the average length of stay or cost per encounter, since this may improperly incentivize stinting on medically necessary care. In those instances where gainsharing programs have been approved, the arrangements have included safeguards that were found adequate to protect against stinting on care or inappropriately changing the case mix (by steering away or cherry-picking patients) or payor mix (e.g.,

[43] OIG, Special Advisory Bulletin, "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries," (July 1999). The Office of Inspector General strongly reiterated its initial position in this Special Advisory Bulletin in a memorandum by D. McCarty Thornton, Chief Counsel to OIG, and Kevin G. McAnaney, Chief Industry Guidance Branch, Office of Counsel to the OIG, "Recent Commentary Distorts HHS IG's Gainsharing Bulletin," August 1999 (stating the clear prohibition in the CMP Law meant that the "only 'favorable' treatment" that OIG could afford for certain gainsharing arrangements would be to exercise prosecutorial discretion to decline to sanction the arrangements).

[44] See OIG Advisory Opinions: 09-06 (June 30, 2009); 08-21 (December 8, 2008); 08-16 (October 14, 2008); 08-15 (October 14, 2008); 08-09 (August 7, 2008); 07-22 (January 14, 2008); 07-21 (January 14, 2008); 06-22 (November 16, 2006); 05-06 (February 25, 2005); 05-05 (February 25, 2005); 05-04 (February 17, 2005); 05-03 (February 17, 2005); 05-02 (February 17, 2005); 05-01 (February 3, 2005).

avoiding lower-paying cases) to achieve cost-saving bonuses.

With respect to the CMP Law,[45] the safeguards generally have included the following elements:

- There is the presence of credible (independent) medical support for the clinical equivalency of lower-cost substitute items in gainsharing programs and for quality standards in pay-for-performance programs
- A clear identification is given of the cost savings, with physician accountability for any adverse effects
- Objective historical and clinical measures are used to establish a floor or baseline threshold below which no savings may accrue for participants
- There is no reduction in compensation if the clinical standard is not medically appropriate for a particular patient
- There is no disproportionate focus on federal health care program patients in the program as opposed to commercially insured patients
- A written disclosure by participating providers is given to patients indicating the providers' participation in the program
- In product standardization cases, the availability of nonpreferred products is maintained, and providers have the same range of product options
- The quality targets selected are commonly used at the particular hospital and are reasonably related to the practice at the hospital, and the patients involved are likely to be treated at the hospital (i.e., patients are not channeled to the hospital so that the participating physicians have the opportunity to gainshare with the hospital on their care)
- The performance measures that may result in bonus compensation are clearly and separately identified, and there is transparency for public scrutiny and individual accountability
- The financial incentives are reasonably limited in duration and amount
- The parties provide for independent monitoring of the quality targets and their implementation

[45] With respect to the CMP Law, the Advisory Opinions have indicated, as the CMP Law provides, that the arrangements must include payments involving a hospital and physician. Payments directly from an insurer to a patient do not implicate the CMP Law. ACOs that include hospitals and physicians and payments designed to limit unnecessary care where a hospital's payment may be reduced or affected by payment to a physician may be viewed as implicating the CMP Law if the payment is deemed to be made by the hospital. See footnote 56 of this white paper.

- Distributions of the shared savings are made to physicians on a per capita basis so no physician has an incentive to generate disproportionate cost savings

Since the CMP Law only applies to payments **by a hospital** to a physician, the only ACOs for which the CMP Law would be a problem are ACOs that are themselves hospitals or that pay participating physicians out of funds that otherwise belong to a participating hospital. These CMP Law issues can be easily avoided by structuring shared savings or gainsharing payments to participating physicians so that they come from an ACO entity that is not a hospital and from funds that belong to the ACO (and not from funds otherwise held by the ACO for a hospital).

The favorable advisory opinions for gainsharing or shared savings programs have also set a pathway for approval of those programs under the AKS, provided that safeguards are included to protect against (a) rewarding referrals, (b) allowing payments to affect medical decision-making, and (c) rewarding physicians for cherry-picking patients. The safeguards described in advisory opinions that have been recognized as adequately addressing these AKS issues include the following:

- The program is not intended to attract new physicians to the hospital to participate in the program; instead all participating physicians must have been on the active medical staff of the hospital (so that the goal of the program is not to establish new referral relationships)
- Participation is broadly available to physicians on the medical staff, not just those who make significant referrals
- The arrangement does not have a disproportionate effect on federal health care programs
- Patient admissions are monitored to protect against changes in referral patterns, including for factors such as severity of illness or payor source
- Distributions of the gainsharing compensation are only made per capita among the physician participants
- There is transparency to help ensure that the goal of the program is quality improvement, not rewarding referrals
- There is a time limit to the program of one to three years
- The participants certify that achieving quality is a critical part of the program and it is not feasible to meet the quality targets without the participation of the physicians
- There is independent oversight to ensure that payments to physicians reward quality not referrals

These favorable advisory opinions furnish guidance on how to structure gainsharing or shared savings programs to comply with the existing AKS and CMP Law standards.

Moreover, in passing PPACA, Congress appears to have embraced shared savings programs. This may help shape future federal AKS and

CMP Law policy in support of these arrangements. As noted above, PPACA specifically amended the CMP Law to authorize programs that promote access to care and pose a low risk of harm to patients and the government.[46] An ACO can always submit a request for an advisory opinion seeking interpretation of this new PPACA amendment to see if CMS and the OIG would now adopt an even more favorable and flexible approach to shared savings programs. Under certain circumstances, PPACA now also specifically authorizes waivers of both the CMP Law and the AKS for ACOs, to encourage the development of ACOs. But any federal waiver will not waive the application of state anti-kickback laws or state laws against stinting on care. So, the above safeguards may be advisable for state law compliance purposes, even if a federal policy is implemented or a federal waiver is obtained.

Safe harbors to the AKS also may be available to protect certain shared savings programs. For integrated systems with employed physicians, the employment exception and employment safe harbor provide broad protection (but there is no similar exception for the CMP Law). The personal services and management agreements safe harbor also may be available in proper circumstances.[47] It may not be possible, however, to structure ACO payment arrangements so that "aggregate compensation" to participating providers "is set in advance." That is, payments may be based on cost savings and performance, including the services provided by others, so that aggregate payments that providers will earn under the program may not be known at the outset — such aggregate compensation would be known only at the end of the year after performance has been evaluated. For this reason, the ACO payment arrangements with independent contractor providers may approximate but not technically meet applicable safe harbor standards. This does not mean that the arrangements are illegal under the AKS, but it does mean that the permissibility of the arrangement will hinge on being able to demonstrate that payments under the program are not intended to induce referrals among ACO participants. To the extent that the ACO can demonstrate through an independent fair-market appraisal or by reference to external benchmarks that payments made to participating providers are within a fair-market value range for the services they provide, this should go a long way toward proving that the payments are intended as fair pay for actual services rendered and toward negating any adverse inference that the payments are intended to improperly induce referrals.

ii. Stark Law

The gainsharing advisory opinions that have been issued have only addressed the CMP Law and the AKS. They have not

[46] See PPACA § 6402(d)(2)(B).

[47] The personal services and management agreement safe harbor has criteria that are similar to the Stark Law exception for personal services. The next subsection (ii) below provides a discussion of these criteria to shared savings programs under the Stark Law that is relevant to application of the AKS safe harbor as well.

addressed Stark Law issues. Some have suggested that there is no Stark Law exception that is sufficiently flexible to allow for gainsharing or shared savings programs.[48]

All the same, gainsharing programs have been implemented under current law and such programs have been structured either to fall outside of the Stark Law prohibitions or to arguably meet the indirect compensation exception or a direct compensation exception, such as the fair market value exception. An ACO arrangement will fall outside of the Stark Law if participating physicians (and their immediate family members) have no direct or indirect compensation arrangement with an entity that provides DHS. This can occur if the ACO is not a hospital (or other DHS entity) — e.g., an IPA, PHO, or other intermediary entity — and payments to the participating physician do not vary with the volume or value of referrals by the physician to any DHS entity participating in the ACO. Most typical shared savings, bundled payment, and capitation arrangements would reward participating physicians for the services they provide; for the quality standards they meet; or for cost savings or quality targets that they help, in aggregate, to achieve — none of which generally involve compensating the physician based on the volume or value of referrals to any DHS entity. Accordingly, any ACO entity that is organized as an intermediary entity, and that is not itself a DHS provider, can potentially be structured so that its financial arrangements with participating physicians fall outside of the Stark Law.

To specifically authorize incentive payment shared savings programs under the Stark Law, in July 2008, CMS issued an additional proposed exception to the Stark Law. The proposed exception, if adopted, would explicitly permit incentive payment and shared savings programs that provide direct financial incentives from a hospital to participating physicians to foster high-quality and cost-effective care while protecting against fraud and abuse.[49] This proposed regulation, if adopted, would create a clear exception to the Stark Law for shared savings programs if 16 separate conditions were all met. There is similarity between the 16 conditions and the safeguards in the advisory opinions discussed above that have approved gainsharing programs under the AKS and the CMP Law.

Among the 16 conditions are the following:

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[48] See 73 Federal Register at 38548 (July 7, 2008) in which CMS states, "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."

[49] The proposed regulation was published in the Federal Register on July 7, 2008, 73 Fed. Register 38502 (July 7, 2008).

- The purpose of the program must be to enhance quality of care through changes in clinical or administrative practices without an adverse effect on quality of care.
- The quality measures must be objective, be supported by medical evidence, be individually tracked, be related to the population served, and be monitored.
- The program needs to require an annual independent medical review of the program's impact on quality of patient care.
- The physicians who participate in the program must have access to the same selection of items, supplies or devices as had been at the hospital prior to the program, and may not be restricted in their ability to make medically appropriate decisions. The hospital may not limit availability of new technology.
- No payment may be made to a physician or physician organization for the use of an item or device if the physician or physician organization has an ownership interest in the manufacture or marketing of the device or item.
- Prior written notice must be provided to patients concerning participation of the providers that informs them of the program and such participation.
- The arrangement must be in writing and must describe the program in detail, including how payments are to be made and what the quality targets are.
- The term of the program must be no less than one year or no more than three years in length.
- Care must be taken to ensure that payments do not relate to quality improvements or cost savings from a prior period.
- No payment may be made for the achievement of cost savings that result in the compromise of patient care quality with respect to achieving a particular targeted measure.
- Payments must be limited in duration and amount and must be measured by comparing the relevant acquisition costs to costs for the year prior to the start of the program.

If all 16 criteria are met, CMS proposed that the Stark Law would not be violated by the shared savings program. The criteria generally are designed to safeguard against stinting on care, steering away undesirable patients, cherry-picking desirable patients, gaming the system, or rewarding referrals. The regulation was proposed in July 2008 but has not been finalized.

Comments submitted to CMS on the proposed regulation have taken various positions: that the proposed exception is not necessary because other Stark exceptions already provide adequate protection for incentive payment and shared savings programs or because those programs can already be structured to fall outside of the Stark Law; that the proposed regulation is too restrictive and does not go far enough in permitting proper

incentive payments and shared savings programs; or that the proposed regulation goes too far and does not provide sufficient protections against perceived abuse. There is no firm indication as to when or if any final regulation will be issued specifically addressing these programs.

Until then, as noted above, ACOs can be structured either to fall outside of the Stark Law altogether or to try to meet an existing Stark Law exception. For example, the Stark Law exception for employment relationships may provide a workable exception for ACOs and other entities that employ all their participating physicians. The employee exception requires fair market value compensation and that the compensation not reward referrals of DHS. The employment exception, however, would not protect any ownership interest that the employed physicians may have in an ACO, like a for-profit hospital, that provides DHS. A separate Stark Law exception, such as the publicly traded securities exception or rural exception would be the only exceptions potentially available to protect such an ownership interest.

Other possible Stark Law exceptions for shared savings programs are the personal service, fair-market value, and indirect compensation exceptions. Again, these are compensation exceptions that do not protect ownership or investment interests in ACOs that are themselves DHS entities. These exceptions generally require that compensation does not vary with the volume or value of DHS referrals, that compensation is set in advance, and that compensation is at fair-market value for the services rendered. In shared savings programs where performance bonuses or savings to be earned are not known upfront, there may be some uncertainty as to whether the requirements of these exceptions may be met. However, programs that specify a fixed-payment methodology, and where aggregate payments to any individual physician are subject to a fair-market value cap, may meet the requirements of those exceptions. An independent appraisal confirming that the program's financial arrangements will yield only fair-market compensation to participating physicians may also help to establish compliance with these exceptions. Finalization of CMS' proposed Stark Law exception for incentive payment and shared savings programs would, however, provide even greater certainty for programs that involve payments to physicians from an ACO that is a DHS entity.

b. Bundled Payments and Capitation

Both bundled payment arrangements and capitation payment systems involve payments to the ACO, which the ACO, in turn, shares with the various provider participants in the ACO. In a bundled payment arrangement, the payment would likely be shared among the providers that provide services as part of the episode of care to which the payment relates. Capitation payments are per capita payments not related to a particular episode of care, but are based on projected care demands of the entire covered population over a set time. The

payment sharing by the ACO to the participating providers under these payment methodologies could take a wide variety of forms, and the form will affect whether the program complies with the Fraud and Abuse Laws.

A key component of the legal analysis will also depend upon the extent to which participating providers continue to have fee-for-service or referral relationships that may be "swapped" for higher ACO payments. For example, a hospital participant in an ACO that receives many referrals outside the ACO arrangement from ACO-participating physicians may elect to accept less of a share of a bundled or capitated payment with the understanding that the referring physicians will make more fee-for-service referrals to the hospital outside of the ACO.

i. AKS

Under the AKS, as mentioned above, payments between the ACO and participants who are employed by the ACO (for example, if the ACO is an IDS with employed physicians) should qualify for the statutory exception and safe harbor protection for payments to employees. Properly structured, compensation to employees could be based on meeting quality targets, personal productivity, or other performance metrics without raising any significant legal risk under the AKS, as long as the resulting compensation is within a fair market value range. Such payments to employees should be protected by the AKS employment exception and safe harbor.

Payment and compensation by the ACO to independent contractor participants in the ACO, however, do not qualify for such protection. Rather, financial arrangements with such independent contractors can be structured to approximate, but probably not fully satisfy, the personal services and management contract safe harbor. Similar to the Stark Law exception for personal services, this safe harbor requires the following:

- The agreement between the paying ACO and provider covers all the services the provider provides to the ACO for the term of the agreement
- The agreement sets the aggregate compensation in advance
- The payment to be made to the participant must be consistent with fair market value
- The compensation is not to be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties
- The services performed do not involve the promotion of an arrangement or business activity that violates state or federal law[50]

[50] 42 C.F.R. § 1001.952(d).

Each of these provisions may present compliance challenges for the ACO, depending on the specific bundling or capitation arrangement. For example:

- If the payment to be made to a participating provider by the ACO depends upon the cost or utilization of care provided by other providers, the aggregate compensation to be paid to the provider may not be able to be set in advance. If not, then it may be difficult to determine in advance whether the payment arrangement is consistent with fair market value standards.
- If there is other business outside of the ACO between the ACO-participating providers, there will need to be assurance that the volume or value of the other business is not swapped for, and does not affect, the payments made to the provider by the ACO.
- The ACO arrangement will need to meet the CMP Law standards discussed above if the arrangement involves any payment from a hospital to a participating physician.

For these reasons, bundled payment and capitation arrangements are unlikely to fit snugly into an AKS safe harbor.[51] However, as discussed above, being outside a safe harbor does not mean the AKS is violated. It just means that the ACO should be well prepared to demonstrate that its payments are not intended to induce referrals among participating providers. With bundled payments and capitation, the intent generally is not to pay for additional referrals, but rather to reduce or limit care to that which is minimally necessary. So, the "bad" intent under the AKS should not be present, absent a swap or other disguised referral arrangement. Again, to minimize AKS risk in structuring bundled and capitation payment arrangements, it is probably advisable to implement the type of safeguards, discussed above, that have been approved by CMS and the OIG in their gainsharing advisory opinions.

ii. Stark Law

Bundled payment and capitation arrangements will also need to be structured to comply with the Stark Law. As noted above, ACO arrangements, including bundled payment and capitation arrangements, can be structured to fall wholly outside of the Stark Law if payments are made to and through an intermediary entity that is not a DHS entity.

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[51] The financial risk-sharing safe harbors to the AKS are unlikely to provide protection. Both bundled payments and capitation put providers at financial risk, both for what the provider furnishes itself, himself or herself, but also for services of other participants. The risk-sharing safe harbors to the AKS are generally designed to provide protection in managed care contracts for reduced premium and cost-sharing amounts paid by beneficiaries or where there is a plan under contract with CMS. See 42 C.F.R. § 1001.952(k), (l) and (m). The bundled payment and capitation programs contain broader relationships not included within these protections.

Otherwise, as with the AKS, the Stark Law contains a broad employment exception that would protect employment relationships between an ACO that is a DHS entity and participating physicians. If the ACO is an IDS in which the physician providers are all employed, there is flexibility to pay the employed physicians without violating the Stark Law[52] as long as there is bona fide employment, the compensation does not reward referrals of DHS and the compensation is at fair market value. Fair-market value should be evaluated against market comparables, and an independent appraisal is advisable if there is any question about the appropriateness of the compensation rates.

The Stark Law also includes an exception for risk-sharing arrangements in the form of withholds, bonuses, and risk pool payments for services by participating physicians to "enrollees" of a "health plan." This Stark Law exception protects risk-sharing payments to the physician that are paid either directly by the health plan or indirectly through an intermediary such as a PHO, IPA, or ACO. Accordingly, ACOs and payors could structure their bundled or capitation payment relationships to meet this risk-sharing exception.[53]

Moreover, academic medical centers have an exception under the Stark Law that some may be able to use in sharing payments with their ACO participants.[54]

Other potential Stark Law exceptions for ACOs include the exceptions, discussed above, for personal services, fair market value arrangements and indirect compensation relationships.[55] ACOs compensating participating providers under any of these exceptions will need to ensure that compensation is set in advance and does not vary with the volume or value of DHS referrals and that there is no violation of the AKS or the CMP Law. The challenges for an ACO to meet these standards are discussed in Section V.A.2.a.i above.

iii. CMP Law

The CMP Law issues for ACOs that use bundled or capitation

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[52] See 42 C.F.R. § 411.357(c).

[53] See 42 C.F.R. § 411.357(n). "Enrollees" and "health plans" are defined in 42 C.F.R. § 1001.952(l)(2). An enrollee is an individual who has a contract relationship with a "health plan" to receive specified health care items and services in return for a payment of a premium or fee (or on whose behalf an employer or other private or governmental entity has a relationship). A health plan is defined as an entity that furnishes or arranges under agreement with health care providers for furnishing health care to enrollees. An entity may include an entity working with authority approved by CMS and a private employer.

[54] See 42 C.F.R. § 411.355(e).

[55] See 42 C.F.R. § 411.357(d), (l) and (p).

payments models are no different than those discussed above for shared savings programs. If the ACO is not a hospital, the CMP Law does not apply to any bundled or capitation payment arrangement with participating physicians. If the ACO is a hospital, or if the arrangement otherwise involves payments by a hospital to participating physicians, then the CMP Law is implicated. To ensure that participating physicians do not stint on care to Medicare patients, if the ACO is a hospital, it would be well advised to avoid generalized cost savings incentives, such as direct capitation payments to participating providers. Such capitation payments incent providers to reduce utilization and cost of services to below budget in order to produce a profit on risk-adjusted per-member per-month payments covering the care of the patient and may encourage participating providers to stint on care. In connection with bundled payments, ACOs that are hospitals would also be well advised to implement the CMP Law safeguards discussed in Section V.A.2.a.i. above that have been recognized by CMS and the OIG in their favorable gainsharing advisory opinions.[56] In addition, such an ACO could seek an advisory opinion under the CMP Law with respect to the PPACA amendment in Section 6402 for programs that improve access to care without posing risk of patient harm[57] or could seek a waiver of federal regulatory requirements, including the CMP Law, for its ACO program.

3. Medicare and Medicaid Risk-Based Managed Care Plans

CMS has indicated that payments made to hospital-physician incentive plans limited to Medicare or Medicaid beneficiaries enrolled in risk-based managed care programs under the Social Security Act are not subject to the CMP Law.[58] The regulatory arrangements for Medicare risk-based managed care contracts,[59] Medicare Advantage contracts,[60] and Medicaid risk contracts[61] are all excepted from the CMP Law but are regulated under regulations specifically applicable to those programs. Such risk-based

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[56] OIG Advisory Opinion 08-16 (October 14, 2008) involved a payment relationship in which an insurer made payment to a hospital and physicians through the private insurer. Under the arrangement, the private insurer made payments to the hospital for meeting specified quality targets. Since the physicians involved were needed to achieve certain of the quality targets, a portion of the payments would be paid to the physician group involved. The sharing of the payments by the hospital and the physician entity was deemed to implicate the CMP Law because money payable to the hospital would go to the physician group. The hospital was deemed to be potentially or indirectly paying the physician group to limit care.

[57] See PPACA §§ 3022 and 3027.

[58] See Letter from Lewis Morris, Assistant Inspector General for Legal Affairs (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm.

[59] 42 C.F.R. § 417.479.

[60] 42 C.F.R. Part 422.

[61] 42 C.F.R. § 438.6.

managed care plans may implement gainsharing and physician incentive programs, subject to the limitations in those program-specific regulations. All the same, hospitals in such plans should be careful in structuring arrangements that may have a spillover effect of inducing limitation or reduction in services provided to patients who are not beneficiaries of such plans.

Applicable regulations permit HMOs and competitive medical plans to subcontract services to physician incentive plans, provided (a) no specific payment is made directly or indirectly to a physician or physician group to reduce or limit **medically necessary** services;[62] and (b) the physicians are not at "substantial financial risk for services they do not furnish," or if they are at such risk, additional requirements are met (e.g., stop loss protection is obtained and specified enrollee surveys are provided). "Substantial financial risk" for services of others is present if (a) withholds greater than 25 percent of the total potential payments are present; (b) there are withholds less than 25 percent of total potential payments if the physician or physician group is potentially liable for amounts exceeding 25 percent of the maximum anticipated total payments to the physician or physician group (if costs or referrals were low enough); (c) bonuses are greater than 33 percent of the maximum anticipated total payments to the physician or physician group (if costs or referrals were low enough) payments minus the bonus; (d) withholds plus bonuses equal more than 25 percent of the maximum anticipated total payments to the physician or physician group (if costs or referrals were low enough); or (e) capitation arrangements, if the difference between the maximum potential payments and the minimum potential payments is more than 25 percent of the maximum potential payment.[63] Other requirements are also involved.

4. Other Fraud and Abuse Issues

There are other Fraud and Abuse Law issues that may be raised by the structure and operation of ACOs.

a. ACO Legal Structural Issues

i. Investment Interests

The legal structure of the ACO may raise issues under the Fraud and Abuse Laws. As noted in Section III above, the ACO may require significant capital to develop its infrastructure and fund its operations, and it may seek equity investors for this purpose.

ACOs structured with equity investors, particularly with those who are referring physicians, may raise issues under the AKS and the Stark Law, since the investor's potential for return on the investment has the capacity to induce referrals either to the ACO itself or to other participating ACO providers. Where the ACO is itself a hospital or provider, it will likely be a participating

[62] Note the inclusion of "medically necessary." This language is not included in the CMP Law.

[63] See, e.g., 42 C.F.R. § 417.479(f).

provider in the Medicare and Medicaid programs. If such an ACO is a provider of DHS (such as a hospital that provides inpatient or outpatient services), then physicians who own equity interests in the ACO will need to qualify for an ownership interest exception under the Stark Law. There is now a Stark Law moratorium on physician ownership of for-profit hospitals, and there are limited exceptions available for ownership interests in ACO provider entities, principally for publicly traded securities and ownership interests in ACOs located in rural areas. However, nonprofit ACO provider entities do not present a Stark Law ownership interest problem, since a membership interest (including a physician membership interest) in a nonprofit generally does not constitute an "ownership or investment interest" for Stark Law purposes. Such membership interests are outside the scope of the Stark Law. Accordingly, while there is broad latitude for structuring physician ownership of nonprofit ACO providers, there are very limited opportunities to have physician ownership of for-profit ACO providers.

It should also be noted that investment interests in ACOs that are providers can implicate the AKS. In this regard, there is an AKS safe harbor for ownership interests in small-business entities and in publicly traded entities. The small-entity safe harbor is available only if the owners of the ACO meet two 40-percent tests. That is, no more than 40 percent of the value of the investment interests for each class of investment interest can be owned by investors in a position to make or influence referrals to, or otherwise generate business for, the ACO (or its affiliates) and no more than 40 percent of the gross revenue related to the furnishing of health care items and services of the ACO can be generated by referrals from investors in a position to refer to the ACO (or its affiliates).[64] This may limit the ability of an ACO that is a provider to include a significant number of physician investors (or other investors that are in a position to refer), even if the ACO is located in a rural area.

ii. IDS

As should be clear from the discussion above, an IDS that employs physicians will have a far easier time complying with the Stark Law and the AKS. Both statutes have broad exceptions (though not absolute) for payments to employees. Further,

[64] 42. C.F.R. § 1001.952(a)(2). Other provisions of the safe harbor are that (a) the terms on which investment interests are offered to a passive investor (defined as one not responsible for day-to-day management and not liable for liabilities of the entity as a general partner or through an agreement) must be no different from the terms offered to other investors; (b) the terms on which interests are offered to those in a position to refer business are not related to previous or expected volume of referrals; (c) no passive investor is required to make referrals or be in a position to make referrals; (d) the entity may not market its services to passive investors differently than to non-investors; (e) the entity may not loan funds to an investor for the investor to make any part of an investment in the entity; and (f) the payment to the investor in return for the investment must be directly proportional to the amount of capital investment. 42 C.F.R. § 1001.952(a)(2). If the entity is located in a defined underserved area, the standards are somewhat more accommodating. 42 C.F.R. § 1001.952(a)(3).

payments within or among an IDS and its wholly controlled entities also generally involve a relatively lower degree of health regulatory risk than payments between and among independent network providers. This is another advantage for IDSs that become ACOs. But, as noted above, IDS arrangements do not provide any greater protection from application of the CMP Law.

b. Anticipated New Regulatory Scrutiny

Improper reporting of quality, cost, or risk-adjuster information (e.g., patient health condition) in connection with shared savings, capitation or other ACO payment methodologies raises the risk of false claims act liability. ACOs that are paid based on meeting quality benchmarks and targets can anticipate that regulators will closely scrutinize ACO reported data on meeting these targets. There will be an incentive for providers to present or interpret data to report success in meeting any targets that are set. ACOs will need to adopt methods to ensure accurate reporting of compliance with the benchmarks and targets.

Also, as ACOs and providers take more risk for providing quality care efficiently, there will be an incentive for the ACO to avoid taking responsibility for the care of the sickest patients. This can happen on an individual basis or by avoiding groups of patients who actuarially present higher risks. The regulators likely will monitor and regulate, no doubt with significant penalties, any such activities ACOs engage in to avoid certain classes of patients. ACOs that try to game the system by accepting only healthier groups or individuals will likely attract regulator scrutiny.

5. Possible Regulatory Modifications Under Health Reform to Increase Flexibility

As described above, under existing law, arrangements can be structured to meet existing legal limitations under the Fraud and Abuse Laws or to significantly reduce the risk of a violation. In certain instances, such careful structuring may inhibit or limit desired flexibility in relationships with providers aimed at improving quality and cost effectiveness and reduce the attractiveness of ACOs. As indicated in the quotation from Lewis Morris, the Chief Counsel of the OIG, in Section V.A.1 above, the government has recognized that new approaches "may be required as new delivery and payment models develop." What may the government do to provide flexibility while protecting legitimate concerns?

Under PPACA, the Secretary is authorized to take a broad-brush approach and simply waive the AKS, the Stark Law, the CMP Law, and other federal restrictions for particular approved payment arrangements.[65] PPACA states that the Secretary's waivers are "permitted in the manner the Secretary determines necessary." The Secretary has the authority to grant a broad waiver for ACOs. But the Secretary also has the authority to permit any ACO structure deemed appropriate under the statute and could exercise

[65] See, e.g., PPACA § 3022(f) and PPACA § 3023(d).

that waiver authority to promote the adoption of otherwise noncompliant but promising ACO arrangements. In granting such a waiver, the Secretary will need to balance legitimate Fraud and Abuse Law concerns regarding payments to physicians and other referral sources with promoting ACO goals, particularly if some of the ACO business continues to be paid on a fee-for-service business. Moreover, such waivers do not extend to state fraud and abuse laws, the requirements of which would need to be met regardless. The state fraud and abuse laws may subject the ACO to the same or similar limitations as under the federal Fraud and Abuse Laws discussed above.

The Secretary has a second approach that can be taken to assist in bridging the gap between present regulatory constraints and successful ACO programs. The Secretary could assess ACO programs on a case-by-case basis under an advisory opinion approach similar to how the OIG presently addresses gainsharing arrangements. However, this approach presents another set of issues. By their terms, advisory opinions only provide absolute protection to the party submitting the request. Also, advisory opinions are often not issued quickly. Delays of up to a year in the issuance of an advisory opinion, as is now the norm, would not well serve the rapid development of ACOs. If ACOs become as popular as some expect, the OIG could be inundated with such requests. It currently does not have enough personnel to process a large volume of such requests.

A third approach would be for the Secretary to create, through regulation, a framework for ACO programs. Any regulatory exception or safe harbor that may be created would apply only to those entities that meet the requirements of an approved ACO. Appropriate standards would be developed through the public notice and comment process.

A fourth approach would be for the Secretary to issue advisory bulletins or guidance that would either announce ACO arrangements that are deemed permissible or specify criteria that the Secretary would apply on a case-by-case basis in granting waivers.

Traditionally, the word "flexibility" is not one that would be associated with government regulation. In this instance, we would encourage the Secretary to permit sufficient flexibility so that ACO arrangements can be structured in straightforward ways to achieve their intended purposes, under a "trust, but verify" regime.

B. Antitrust Issues

In the past few years, both federal antitrust enforcement agencies (the Agencies) have dedicated resources to helping health care organizations innovate alignment arrangements within the bounds of the antitrust laws. The Federal Trade Commission (FTC) has held workshops[66] and issued widely read advisory letters on clinical integration, and the United States Department of Justice (DOJ) Antitrust Division announced in 2009 that it, too, would review

[66] See "Clinical Integration: A Check-up," May 29, 2008, workshop, available at http://www.ftc.gov/bc/healthcare/checkup/index.shtm.

clinical integration proposals to encourage providers to explore these competition-enhancing arrangements. At the same time, the Obama administration has indicated that health care is one area in which its antitrust enforcement efforts will be concentrated, and health care organizations continue to be investigated and sanctioned for anticompetitive practices such as collective negotiations with insurers by physician and hospital cooperatives[67] that, seen in broad strokes, do not look entirely different from the types of integration arrangements that the Agencies have urged providers to actively pursue. Even as the Agencies encourage collaboration by integrated providers, they maintain a healthy dose of public skepticism about the pro-competitive impact of many provider collaborations. As Assistant Attorney General Christine Varney, the head of the DOJ Antitrust Division, recently opined, "Where purported efforts to integrate are principally a vehicle for exploiting or maintaining market power or simply a subterfuge for price fixing, then antitrust is there, as it should be, to protect competition and consumers."[68] The head of the FTC, Jon Liebowitz, put it even more bluntly: "If you fix prices — that is, if independent doctors jointly negotiate the fees they charge — we will make you stop. But if you join together to improve patient care and lower costs, not only will we leave you alone, we'll applaud you."[69]

The enactment of PPACA and the dawn of the era of the ACO only brighten the spotlight on this area of innovation and regulation with its attendant opportunities and antitrust risks. While the promotion of ACOs in PPACA should be seen as a public policy endorsement of the pro-competitive potential for these collaborations, there can be no doubt that ACO arrangements will be met with wariness and scrutiny by the Agencies. Already the FTC has signaled that it intends to play an active role in shaping policies governing ACOs, and it will hold a health care competition policy workshop in the fall of 2010 that will focus on ACOs.[70] Understanding the Agencies' existing contours of antitrust risks associated with ACOs will be important for any organization interested in pursuing ACO status. The current antitrust status of ACO arrangements is discussed below.

1. Foundational Principles

The Agencies have compiled a significant body of guidance for the health care industry, perhaps recognizing that it is an area that is uniquely susceptible to effective competition regulation. The main source of guidance on what kinds of collaborative conduct will and will not give rise to antitrust liability are the Statements of Antitrust Enforcement in Health

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[67] See, e.g., "Minnesota Health Care Provider Group Settles FTC Price Fixing Charges," http://www.ftc.gov/opa/2010/06/ruralhealth.shtm.

[68] "Antitrust and Health Care," remarks to the American Bar Association/American Health Lawyers Association Antitrust in Healthcare Conference by Christine A. Varney, Assistant Attorney General, DOJ Antitrust Division, May 24, 2010 (Varney Remarks), at 7.

[69] "A Doctor and a Lawyer Walk into a Bar: Moving Beyond Stereotypes," remarks to the American Medical Association House of Delegates by Jon Leibowitz, Chairman, FTC, June 14, 2010 (Leibowitz Remarks), at 7.

[70] See Leibowitz Remarks at 7.

Care (Health Care Statements), jointly issued by the FTC and DOJ in 1996.[71] In addition, there are numerous advisory letters issued to would-be collaborators, as well as useful information in enforcement documents and, of course, foundational judicial opinions.

All this guidance proceeds from the starting point that collaboration by health care providers is unlawful under Sherman Act Section 1, 15 U.S.C. Section 1, when it runs afoul of the prohibition of any contract, combination, or conspiracy that unreasonably restrains trade.[72] Most typically this occurs when groups of health care providers that are not sufficiently integrated jointly negotiate fees with insurers.[73] Sufficient integration may be either clinical integration, i.e., the maintenance of standards, practices, and protocols that go directly to the means of care delivery, or financial integration, i.e., the sharing of risk in contracting in order to provide incentives to enhance efficiency. The federal courts and the Agencies have repeatedly found joint fee negotiation by nonintegrated providers — which are not substantially financially or clinically integrated — to constitute naked price-fixing among competitors, a *per se* violation of the Sherman Act.

Nonetheless, the Agencies have recognized that, in the presence of sufficient integration, cooperation among providers is an important avenue for improving the efficiency of health care delivery and the quality of health care itself. Not surprisingly, the principles that collaboration among providers can be pro-competitive and that sufficient integration is the key to making sure that provider collaboration aids rather than hampers competition are also reflected in PPACA. PPACA permits only highly clinically integrated ACOs or ACOs that are adequately sharing financial risk (such as through partial or global capitation programs, bundled payments, or shared savings programs) to participate in governmental payment programs. Because PPACA was drafted in light of the existing body of antitrust law governing provider collaborations, and because the Agencies have already indicated that they consider ACOs to be within their regulatory purview,[74] it is fair to assume that the guidance thus far issued by the Agencies will continue to be applied to ACOs.

a. Single Entities

Under the Sherman Act Section 1, a plaintiff must show that the challenged arrangement is a "contract, combination, or conspiracy" between at least two entities that unreasonably harms competition. In

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[71] Statements in Antitrust Enforcement in Health Care, FTC and DOJ, 1996, available at http://www.justice.gov/atr/public/guidelines/0000.htm (hereinafter "Health Care Statements").

[72] 15 U.S.C. § 1.

[73] See *Arizona v. Maricopa County Medical Society*, 457 U.S. 332 (1982).

[74] See Varney Remarks at 2 ("There can be no doubt that the success of ... ACOs will depend, in large part, on effective competition, both among health care insurers and providers. Moreover, clear and accessible guidance on antitrust issues associated with [ACOs] can also contribute to their success.").

Copperweld Corp. v. Independence Tube Corp.,[75] the Supreme Court established that where the entities alleged to have collaborated are in fact a single enterprise, Section 1 is not implicated. In the health care context, if a joint venture can show that it is in fact a single enterprise, the concerns about the collaboration violating the antitrust laws are not present.

As the Supreme Court recently pointed out in *American Needle, Inc. v. National Football League*,[76] however, demonstrating that collaborators are in fact a single enterprise is not always a simple task. In that case, the Court rejected the NFL's claims that all NFL teams functioned as a single enterprise for purposes of negotiating intellectual property rights and held that in determining whether entities comprised a single enterprise or multiple enterprises, the inquiry should be multifold. Specifically, instead of focusing solely on the formal legal status of the individual entities, the court endorsed a functional approach to determining whether the entities in practice act as independent decision-makers and economic actors.[77]

The holding of *American Needle* underscores the difficulty in relying on single-enterprise status to avoid antitrust liability but does not foreclose the availability of this protection where distinct entities can demonstrate a high degree of functional unity with respect to their operation and economic interests.[78] For instance, where multiple entities are run by a single board, operate with a unified budget, employ staff through the larger organization, and coordinate all services, there is less risk that the entities will be found not to be a single enterprise for antitrust purposes.[79]

2. Guidance From the Enforcement Agencies

a. Guidance on Financial Integration

The Health Care Statements make clear that a joint venture may not run afoul of the antitrust laws where the participants share "substantial financial risk"[80] with sufficient incentives to deliver care efficiently or bear the losses associated with waste. This level of so-called financial integration is "a clear and reliable indicator ... of sufficient integration ... to achieve significant efficiencies,"[81] such that

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[75] 467 U.S. 752, 767-68 (1984).

[76] 560 U.S. __ (May 24, 2010), available at http://www.supremecourt.gov/opinions/09pdf/08-661.pdf.

[77] See generally id. at 5-15.

[78] See, e.g., *HealthAmerica Pennsylvania, Inc., et al. v. Susquehanna Health Sys.*, et al., 278 F. Supp. 2d 423, 433-36 (M.D. Pa. 2003).

[79] Id.

[80] See Health Care Statements, Statement 8(A)(4).

[81] Id.

true risk-sharing ventures are not likely to be found to violate the antitrust laws even in absence of "clinical integration," discussed *infra*.

As FTC officials have noted, "The underlying justification for a 'financial integration' and a 'clinical integration' test is similar (potential for improved efficiencies), but the former seems to rely on the existence of incentives to improve whereas the latter seems to rely on the stated plans for improvement."[82] Therefore, the effectiveness of the incentives is likely to determine whether a joint venture is sufficiently financially integrated. In noting that "[r]isk sharing provides incentives for the physicians to cooperate in controlling costs and improving quality by managing the provision of service by network physicians,"[83] the Health Care Statements contemplate and permit certain ACO payment arrangements set forth in PPACA. The Health Care Statements provide the following examples of financial arrangements that involve substantial financial risk: provision of services for a capitated rate negotiated with a health plan; provision of services for a negotiated percentage of premium payments or plan revenue; significant goal-based compensation to reward group or network-wide performance measured by quality of care and efficiency of delivery; and provision of care through an "extended course of treatment" requiring coordination of specialists for a predetermined payment, regardless of a particular patient's profile.[84]

b. The Health Care Statements and Safety Zones for Financially Integrated Joint Ventures

The Health Care Statements, specifically Statement 8, set forth what level of financial integration, in the presence of other characteristics, may cause a joint venture to fall within a "safety zone" such that it will not violate the antitrust laws. The safety zones articulated in the Health Care Statements provide critical guidance for health care providers considering collaborative ventures.[85] As a threshold matter, the Agencies will apply different standards to joint ventures deemed "exclusive" and "non-exclusive"[86] when determining whether the joint venture falls into the safety zone. "Exclusive" joint ventures are those in which the participating physicians are by requirement or in practice barred from entering into contracts with health plans on an individual basis or joining other networks. "Non-exclusive" joint ventures are those in which physicians can or do join other networks or enter into

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[82] Remarks of Thomas B. Leary, Commissioner, FTC, "The Antitrust Implications of 'Clinical Integration': An Analysis of FTC Staff's Advisory Opinion to MedSouth," Saint Louis University Health Law Symposium (April 12, 2002).

[83] Id.

[84] Id.

[85] See generally Health Care Statements, Statement 8(B).

[86] Health Care Statements, Statement 8(A).

contracts with health plans on an individual basis.[87] The Health Care Statements provide that the enforcement agencies are not likely to challenge an exclusive joint venture if the participating physicians share substantial financial risk and constitute 20 percent or fewer of the physicians in each physician specialty with active hospital staff privileges who practice in the so-called relevant market when defined geographically.[88] The 20-percent limit may be exceeded in situations where there are fewer than five physicians in a particular specialty in the relevant market, so long as the specialist is included in a non-exclusive basis.[89]

With respect to non-exclusive joint ventures, the Health Care Statements set forth that the enforcement agencies are not likely to challenge joint ventures in which participating physicians share substantial financial risk and constitute 30 percent or fewer of the physicians practicing in a given specialty practicing in the relevant geographic market.[90] If fewer than four physicians practice in a particular specialty in the relevant geographic market, a non-exclusive joint venture that would otherwise fall into the safety zone can include one physician practicing in that particular specialty, despite the fact that the physician's participation means that the participants in the joint venture make up more than 30 percent of the physicians in that specialty in the relevant market.[91] Based on case law and Agency precedent, the size of ACO networks need not be limited to the 20-percent exclusive/30-percent non-exclusive safety zone in order to pass antitrust muster.

The Health Care Statements also provide substantial guidance regarding what constitutes sharing of substantial financial risk among

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[87] For a more detailed description of what will be considered to be a "non-exclusive" venture, see Health Care Statements, Statement 8(A)(3) (setting forth "indicia of non-exclusivity").

[88] Health Care Statements, Statement 8(A)(1). For more detailed information on what constitutes sharing of financial risk, see Statement 8(A)(4). The Health Care Statements describe the definition of "relevant market" in Statement 8(B)(2) as follows:

The [enforcement agencies] evaluate the competitive effects of a physician network joint venture in each relevant market in which it operates or has substantial impact. In defining the relevant product and geographic markets, the Agencies look to what substitutes, as a practical matter, are reasonably available to consumers for the services in question. The [enforcement agencies] will first identify the relevant services that the physician network joint venture provides. Although all services provided by each physician specialty might be a separate relevant service market, there may be instances in which significant overlap of services provided by different physician specialties, or in some circumstances, certain nonphysician health care providers, justifies including services from more than one physician specialty or category of providers in the same market. For each relevant service market, the relevant geographic market will include all physicians (or other providers) who are good substitutes for the physician participants in the joint venture.

[89] Id.

[90] Health Care Statements, Statement 8(A)(2).

[91] Id.

physicians.[92]

3. Clinical Integration

Even if a joint venture does not fall into the safety zones — for instance, by including a higher percentage of participating physicians in a given specialty — the Health Care Statements make clear that such a venture still may be permissible under the antitrust laws. If a joint venture is "not anticompetitive on balance," a determination made by looking at the potential pro-competitive effects and the potential anticompetitive effects of a joint venture, it is not likely to face challenge by the Agencies.[93] This analysis is known as the "rule of reason." In the context of joint ventures, it is applied to determine (1) whether the arrangement benefits consumers (in terms of quality of care and cost) enough to outweigh the potential harm in allowing competitors to collaborate and (2) whether the aspects of the arrangement that threaten competition are necessary to capture the benefits of the arrangements.

As made clear by the Health Care Statements, the Agencies measure the risks and benefits of joint ventures by looking at whether "consumers will have the benefit of high quality, cost-effective health care and a wide range of choices" in the face of such arrangements.[94] One of the primary means of avoiding liability under the antitrust laws, even when a joint venture is outside of the "safety zones," is to show that these pro-consumer benefits are achieved through clinical integration.

Although the Antitrust Division at the DOJ has recently indicated that it will also conduct reviews of proposed joint ventures featuring clinical integration,[95] the FTC has been issuing detailed opinion letters on clinical integration and pursuing agency actions for several years. The archive of FTC opinion letters makes clear that the agency takes a hard look at the claimed efficiencies of clinical integration and whether it is necessary to jointly contract to achieve those efficiencies. Based on the FTC's statements, it is reasonable to believe that a permissible clinical integration program must include the following basic elements:

- Integration of institutions and practitioners that presents the opportunity for true collaboration and productive sharing of information reflecting actual "interdependence"
- Participation of both specialists and primary care physicians with a requirement of in-network referrals

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[92] Health Care Statements, Statement 8(A)(3).

[93] Health Care Statements, Statement 8(B).

[94] Id.

[95] Letter to Sen. Patrick J. Leahy from Ronald Weich, Assistant Attorney General, U.S. Department of Justice (December 10, 2009) (setting forth target date of February 2010 for review program for entities wishing to pursue clinical integration), available at http://www.aha.org/aha_app/issues/Clinical-Integration/advocacy-clinical-integ.jsp.

- Treatment of a broad spectrum of diseases and disorders and corresponding clinical protocols
- Integrated information technology whereby network participants can efficiently exchange information regarding patients and practice experience
- Integrated information technology whereby utilization and claims information can be gathered, analyzed, and communicated in order to improve treatment quality, rates of utilization, and cost containment
- Integrated information technology whereby physician compliance and performance, in accordance with collective, physician-authored benchmarks and standards, may be measured
- A high level of physician investment, both economically and in terms of time for training and utilization of the system, and agreement among physicians to comply with the standards, benchmarks, and protocols put in place by the network
- Enforceable consequences for noncompliance by physicians and institutions, and systems for improving performance and compliance

This list is not exhaustive, however, and the most important piece of guidance issued by the FTC is that it will "focus on substance, rather than form, in assessing a network's likelihood of producing significant efficiencies."[96] In other words, it will assess the impact of the clinical integration efforts on utilization, cost and quality in real rather than hypothetical terms.[97]

The existence of sufficient clinical integration does not, by itself, guarantee that joint contracting by a physician network will pass muster under the antitrust laws. As evidenced by the guidance gleaned from the FTC's decisions noted above, joint contracting must be reasonably necessary to accomplish the goals of the clinical integration plan, and the FTC will look carefully to see if there are alternative means of achieving efficiencies, other than joint contracting, that do not threaten competition. Based on the FTC's statements, the following further features of a clinical integration program would appear to reduce antitrust risk:

- It should be non-exclusive and allow for independent contracting where payors and the network cannot come to agreement on terms, as this greatly reduces the chances that the arrangement will present significant antitrust risk
- It should not involve unnecessary exchange of pricing information among physicians and hospitals

[96] Health Care Statements, Statement 8.B.1.

[97] An additional helpful source of summary-level guidance is the American Medical Association's publication, "Competing in the Marketplace: How Physicians Can Improve Quality and Increase Their Value in the Health Care Market Through Medical Practice Integration," (2d ed. 2008), available at http://www.ama-assn.org/ama1/pub/upload/mm/368/competing-in-market.pdf.

- Price setting should be in effect only for those services that are part of the clinically integrated program

4. Multiprovider Networks Including Hospitals

The Health Care Statements, Statement 9 covers "multiprovider" networks such as those involving both hospitals and physicians. Because of the complexity of these arrangements — in terms of the contractual arrangements, spectrum of providers and the efficiencies presented — and the fact that there is a great deal of development and variety in this area, the Agencies have not established any "safety zone" for multiprovider networks. Therefore, the antitrust analysis is somewhat more nuanced than that applied to the joint ventures discussed above.

The Health Care Statements provide that where entities in different provider categories that would otherwise compete in a relevant market financially or clinically integrate in a joint venture, pro-competitive efficiencies may result. Where the agreements among these competitors are "reasonably necessary" to accomplish the pro-competitive benefits of an integration, the efficiencies and potential anticompetitive effects are weighed to see whether, on balance, the arrangement is pro- or anticompetitive.[98] This analysis is complex and cumbersome and requires definition of the relevant market, identification of efficiencies, the practical ability of the network to raise prices above competitive levels, and the ancillary effects of the arrangement in other markets.[99]

The obvious conclusion that can be reached from the above brief antitrust analysis is that, if the network is not too large and has substantial financial integration, and there are identifiable efficiencies created by the arrangements and few if any ancillary or direct anticompetitive effects, there is little risk of an antitrust challenge. But, as noted above, the Agencies focus on substance, not form, in assessing a network's likelihood of producing significant efficiencies.

With respect to collaborative bargaining, which in and of itself rarely benefits consumers and may be characterized as illegal price-fixing, the challenge is to demonstrate that collaborative bargaining is integral to the clinical integration scheme such that the countervailing advantages cannot reasonably be achieved without it. Generally speaking, this requires the creation of a contracting structure that facilitates and requires a high degree of interdependence and cooperation among participating providers that share material financial risk. In other words, the Agencies must find that the collaborative bargaining aspect of the arrangement is a "necessary evil" required to achieve significant benefits for consumers.

5. Messenger Model Pricing

If the participating providers in the ACO are not able to or do not achieve

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[98] Health Care Statements, Statement 9(A).

[99] Id.

substantial financial and/or clinical integration, then the ACO can resort to pricing, utilizing a messenger model, on behalf of participating providers in the ACO. Under a messenger model arrangement, participating providers that are independent in a network (here, the ACO) typically give the network a limited right of first opportunity to attempt to contract with payors on behalf of each participating provider. The longer the right of first opportunity period, the greater the risk that the period will be viewed as an unreasonable restraint on competitive pricing. Under the messenger model, the network (or its agent) also typically does not have direct contracting authority (so-called single-signature authority) on behalf of participating providers. Rather, each participating provider must sign its own payor contract once an agreement is reached.

There are two varieties of messenger model arrangements: the "pure" messenger model and the so-called modified messenger model.

a. Pure Messenger Model

Under the pure messenger model, the ACO (or its agent) serves as a "messenger" to communicate offers from payors to participating providers and to communicate the providers' responses back to the payors. The providers retain the right unilaterally and independently to accept, reject or counter the payor offer. Generally, the ACO will need to give the providers the opportunity to consider the payor's offer and cannot reject it out of hand. Essentially, the ACO simultaneously conducts separate negotiations on behalf of each of its independent participating providers. Once agreement is reached, participating providers can either opt in or opt out of the contract. Opt-in arrangements require affirmative, separate consideration and approval by participating providers and carry less antitrust risk than opt-out arrangements. Under opt-out arrangements, the participating provider is deemed to have approved the contract and defaults to participating in the contract, unless the provider affirmatively opts out.

b. Modified Messenger Model

Under modified messenger model arrangements, participating providers each designate in advance to the ACO the price point that the provider would accept from the payor (e.g., 130 percent of the Medicare allowable for a particular service or item). Each of the providers should unilaterally and independently determine their own acceptable price points without collusive discussions or agreements with other participating providers or the ACO. The participating provider typically agrees in a participation agreement that if the payor offers a contract with pricing at or above the provider's specified pricing, then the participating provider will be bound to accept and sign the contract. If the payor does not offer that pricing, the ACO may reject the contract offer on the participating provider's behalf. Otherwise, the modified messenger model process is substantially the same as the pure messenger model arrangement.

c. No Price Information Sharing

The ACO (or its agent) cannot share with participating providers the

prices that participating providers are willing to accept for their services, and the ACO (and its agent) cannot otherwise facilitate pricing collusion among participating providers. Rather, the ACO (or its agent) must act as a "black box" — that is, pricing information that goes in from one participating provider cannot go back out to any other participating provider. Some national payors have gotten aggressive in challenging messenger model arrangements that appear to be facilitating common pricing or that use a common agent that has not implemented adequate black box policies to ensure that there is no leakage of pricing information to participating providers.

d. Weaknesses of the Messenger Model

While the messenger model was once seen as a promising paradigm, it has over the years fallen into disfavor as being inefficient, burdensome, and, in some cases, anticompetitive, where the participating providers do not adhere to the strict requirements for avoiding the formation of an actual price-fixing agreement among competitors.

Moreover, the weakness of messenger model arrangements is that a motivated payor can do an end run around the network and require separate direct negotiations with each participating provider. All that the payor needs to do is wait out the right of first opportunity period, at the end of which the payor can directly approach participating providers to negotiate contract rates. The network, at that point, has no contractual right to stop the provider from separately negotiating and contracting with the payor and would risk facilitating an illegal "group boycott" if the network exhorted participating providers or otherwise tried to influence them collectively not to negotiate or contract with the payor.

6. Recommendation for Modification of Antitrust Health Care Guidelines to Coincide With PPACA

To encourage the efficient adoption of a pro-competitive ACO model, it is possible for the Agencies to take a more proactive approach than merely referring would-be ACOs to the existing Health Care Statements and clinical integration advisory letters. To capitalize on the swell of interest in pro-competitive collaboration among health care providers in the wake of PPACA, the Agencies may well consider creating an additional safety zone for ACOs, i.e., multiprovider networks that achieve PPACA's goals of improving quality of care while controlling the rate of increase in health care cost. The description of the safety zone could clearly synthesize the existing advice regarding the degree and kind of integration necessary to achieve pro-competitive benefits (as, we note, several commentators, including Foley & Lardner LLP attorneys, have advocated[100]) to make clear

[100] See Holden Brooks, David W. Simon, Chris E. Rossman, "Clinical Integration: A Guide to Working with the Federal Trade Commission to Enhance Care Through Pro-Patient, Pro-Innovation, Pro-Efficiency Provider Networks," *Health Lawyers Weekly*, The American Health Lawyers Association, January 30, 2009, Vol VII Issue 4, available at http://www.foley.com/publications/pub_detail.aspx?pubid=5632.

that as long as conduct falls within the safety zone, and absent extraordinary circumstances, the Agencies would not prosecute a compliant, integrated ACO. We believe that the Agencies have the power to articulate a new safety zone for an ACO that is designed to achieve the goals of PPACA and that swift publication of this kind of guidance would serve the interests of both providers and consumers.

C. State Law Considerations

1. Regulation as Insurance

Bundled payments and shared savings plans are generally considered a variant of fee-for-service arrangements that do not involve the assumption of insurance risk. Therefore, such payment arrangements are not usually regulated as insurance under state insurance law.

However, when health care providers enter into certain types of reimbursement arrangements (e.g., capitation arrangements) that result in the health care providers becoming "risk bearing" entities, they often become subject to state insurance or managed care regulation. In such situations, failure to obtain a license or certificate of authority from state insurance regulators is typically a violation of a state law. Therefore, ACOs must be aware that should they become a "risk bearing entity," licenses, registrations, and compliance with certain regulatory restrictions may be required.

The National Association of Insurance Commissioners (NAIC) addressed the issue of capitation in the mid-1990s during the rise of ACOs' precursors: IDSs, PHOs, and IPAs. Generally, it was determined that where a health care provider accepts a fixed prepayment to provide future health care services to a set group of patients, the health care provider is assuming insurance-type risk. However, in most states, the health care provider that accepts capitation payments is not subject to insurance regulation if the health care provider only accepts "downstream risk" from a duly licensed insurer. Thus, a health care provider is often allowed to enter into an arrangement with a licensed insurer or other regulated risk-bearing entity, such as an existing HMO, to provide services to the enrollees of the HMO in exchange for a fixed capitation payment. The rationale for allowing this assumption of downstream risk is that the enrollees of the risk-bearing HMO are covered by the solvency and consumer protections of the state's insurance laws, should the health care provider become insolvent. The notable exception is risk-bearing health care providers in California, which are subject to limited Knox-Keene licensure, even if they contract for capitation payment through a licensed managed care entity like an HMO.

If the health care provider entity contracts with a self-funded, employer-sponsored (ERISA-qualified) health plan on a capitation or other risk-bearing basis, then the provider entity will be directly subject to the various state managed-care laws and regulations. This is because ERISA plans are not subject to state regulation and there is no other protection for consumers if the risk-bearing health care provider entity goes belly-up.

In this regard, every state has adopted some form of managed care or

insurance regulation that would apply if the health care provider entity contracts with an ERISA plan on a risk-bearing basis. These regulations often impose a number of requirements on the duly licensed or registered entities, which may be burdensome to an ACO:

- Minimum capital requirements of $2,500,00 or more to ensure solvency
- A required fidelity bond of $1,000,000 or more
- Approval of all marketing materials, provider contracts, forms, and rates
- Required disclosures to enrollees
- Annual reporting requirements
- Requirements regarding types of care provided and how such care can be rationed
- Exposure to examinations of the ACO's affairs at least once every five years

Therefore, those considering ACO formation will have to carefully consider state laws in those states where patients/practices are located, to determine if the acceptance of risk under a capitation payment or similar system, particularly from an ERISA-qualified plan, will result in regulation under the applicable state's insurance or managed care laws and regulations.

2. Corporate Practice of Medicine

Most states prohibit what is generally referred to as the "corporate practice of medicine" (CPOM). There are a few states like Florida, Utah, and New Mexico that do not have any CPOM restriction and where any form of ACO could directly employ physicians and other providers.

Generally, though, the CPOM prohibitions in most states would not allow business corporations or other nonmedical practice entities (e.g., entities other than professional corporations) to practice medicine or to employ a physician to provide professional medical services. In some states, CPOM prohibitions include certain exceptions. For example, nonprofit hospitals are allowed to employ physicians in many CPOM states, because a hospital has been formed for the express purpose of treating patients and providing health care. This is not true, however, in all CPOM states — e.g., Illinois and California do not permit hospitals to directly employ physicians. Accordingly, parties organizing an ACO should review the CPOM doctrine in each relevant jurisdiction to see what effect, if any, it might have on an ACO's organizational structure. As a general rule, as control and/or interaction by nonlicensed practitioners with medical decision-making with a physician entity increases, there is greater risk for violation of the CPOM rules in those states that have CPOM restrictions.

In states with strong prohibitions on the corporate practice of medicine, friendly physician professional corporations, foundation model arrangements, PHOs, management service organizations, or other independent contractor arrangements may be used to structure relationships with physicians.

D. Tax Issues

As noted above, the legal structure of the ACO can take many forms. The tax consequences to the parties will necessarily flow from the selected legal structure. If a flow-through entity (limited liability company [taxed as a partnership], partnership, or Subchapter S corporation) is used, the parties will report all tax items on their own returns. If a corporation is used, it will be taxed on any net taxable income, unless it can qualify for tax-exempt status.

1. ACO Qualification for Tax Exemption

It may be challenging for a stand-alone entity serving as an ACO to obtain tax-exempt status. In order to obtain tax-exemption under Section 501(c)(3) of the Internal Revenue Code,[101] the ACO entity must be organized and operated exclusively for charitable or scientific purposes.[102] If the ACO provides services to patients, and it is properly formed (as a nonprofit entity that meets the other requirements under the Code[103]), it may be able to obtain tax-exempt status if it meets a "modified" community benefit standard.[104] In addition, if all the participants in the ACO themselves are related Section 501(c)(3) organizations, the ACO may be able to qualify as a tax-exempt entity under the integral part test that is commonly used by parent organizations in IDSs.[105]

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[101] References to Internal Revenue Code or Code Section are to the Internal Revenue Code of 1986 as amended through the date of this publication.

[102] There are other categories of entities that qualify under Section 501(c)(3), such as religious, literary, educational, testing for public safety, and fostering national or international amateur sports, that are not relevant to this discussion.

[103] In order to qualify under Section 501(c)(3), an entity must be organized and operated exclusively for one or more of the purposes enumerated in the Code, no part of the net earnings of the entity can inure to the benefit of any private shareholder or individual, no substantial part of the activities of the entity can consist of carrying on propaganda or influencing legislation, and it cannot participate or intervene in any political campaign on behalf of or in opposition to any candidate for public office.

[104] The community benefit standard is generally set forth in Rev. Rul. 69-545, 1969-2 C.C. 117. This ruling sets forth factors to be considered in determining if a hospital qualifies for tax-exempt status and includes (1) whether the governing body is composed of members of the community as opposed to financially interested individuals; (2) whether medical staff privileges are available to all qualified physicians in the area, consistent with the size and nature of the facility; (3) whether there is a full-time emergency room open to all regardless of ability to pay; and (4) whether the facility admits patients who are able to pay for their care themselves or through third-party payors such as private health insurance or government programs such as Medicare and Medicaid. Other factors may also be instructive, such as whether the facility conducts medical research, educates the public regarding health care matters, or provides types of health care services not otherwise available to the community.

[105] An organization will qualify under the integral part test if the organization (1) is structurally or financially related to a Section 501(c)(3) entity that it supports and (2) performs an essential service for that entity. See Rev. Rul. 78-41, 1978-1 C.B. 148. Structural relatedness requires the exempt organization to exercise control and closely supervise the ACO. Financial relatedness requires that the financial decisions of the ACO be made at the direction of the supported Section 501(c)(3) entity. An essential service is an activity in which the Section 501(c)(3) entity could engage without jeopardizing its tax-exempt status and without such activity being characterized as an unrelated trade or business activity. In addition, the essential service must be provided directly to the supported Section 501(c)(3) entity or to the direct beneficiaries of an affiliate.

A nonprovider ACO will face greater challenges to obtain tax-exempt status. There is no existing guidance for tax exemption for ACOs. Merely providing contracting or coordination services (e.g., IPA, PHO, or MSO services) for a variety of organizations (even if all participants are tax exempt) has not been recognized by the IRS as an inherently charitable activity.

The IRS has considered the eligibility for exempt status of many nonhospital entities that operate within the health care industry. Almost all are analyzed under a modified version of the community benefit standard. PHOs generally cannot qualify for exemption under Section 501(c)(3), because they do not directly provide health care services, and since they provide marketing services to private, for-profit parties, there is most likely substantial private benefit.[106] MSOs have been similarly analyzed by the IRS.

In analyzing HMOs, the IRS has noted that there are basically four rationales for tax exemption: (1) promotion of health; (2) relief of the poor and distressed; (3) lessening the burdens of government; and (4) satisfying the requirements of the integral part doctrine. The IRS has concluded that an organization must be a direct provider of health care services to fit within the first rationale of "promotion of health."[107] An HMO may qualify for tax-exempt status if it serves the health care needs of Medicaid patients, since Medicaid beneficiaries consist of those who are "poor and distressed." In order to meet the "lessening the burdens of government" rationale, the organization must perform functions that otherwise would have to be provided by the federal, state, or local government, so the organization's performance of those functions actually lessens the governmental burden.[108] In determining if a function is a burden of government, there must be an objective manifestation by the government that it considers such an activity to be part of its burden.[109] Whether the organization's activities "lessen" the burdens of government is a facts and circumstances test, as it focuses on the particular activities conducted by the organization and not on its purposes. The fourth rationale, integral part, has been discussed above.

It is unlikely that ACOs will focus solely on providing or facilitating medical services to the poor and distressed. It is also highly unlikely that the services provided by an ACO will be characterized as lessening the burdens of government. Finally, since most ACOs will involve the participation of a large number of unrelated entities, it will be unlikely that the integral part test can be met. Consequently, it will be very difficult for a stand-alone ACO

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[106] See discussion of private benefit below in D.2 of this Section V.

[107] See "Exempt Organizations, Continuing Professional Education Technical Instruction Program for FY 1999," p.67.

[108] See Rev. Rul. 85-2, 1985-1 C.B. 178.

[109] The attitude of the governmental unit is the only reliable indicator of what the government determines to be its burden. If a particular activity has been engaged in by a governmental unit on a regular basis for a significant length of time, it may be apparent that the activity is a burden of government. See Rev. Rul. 74-117, 1974-1 C.B. 128.

to obtain tax-exempt status. However, an ACO that is a support organization to an existing tax-exempt hospital or health care organization should be able to qualify for tax exemption.

2. Private Inurement and Private Benefit

In order to qualify and maintain Section 501(c)(3) status, an organization must avoid private inurement and substantial private benefit.[110]

In order to avoid the prohibition on substantial private benefit, the organization must establish that it is not organized and operated for the benefit of private interests, such as designated individuals; the creator or his/her family; shareholders of the organization; or persons controlled, directly or indirectly, by such private interests. However, the prohibition on private benefit is not limited to "insiders" — it applies to any individual, whether or not the individual is in a position of influence over the organization. There is some private benefit inherent in the charitable activities of a Section 501(c)(3) organization. For example, charity care patients receive a private benefit when they receive free health care services. Private benefit provided to members of such a charitable class is generally considered incidental to the public purposes of the provider organization. To be incidental, private benefit must not be substantial when compared to the overall community benefit provided by the activity, and it must be a necessary result of the activity which benefits the public. The word "incidental" has both qualitative and quantitative connotations. In order to be qualitatively incidental, the benefit must be a necessary concomitant of the activity which benefits the public at large — the benefit to the public cannot be achieved without necessarily benefiting certain private individuals.[111] The quantitative element requires that the private benefit not be substantial after considering the overall public benefit conferred by the activity.[112]

Inurement is a specific kind of private benefit. It arises whenever a financial benefit represents a transfer of the organization's financial resources to an individual solely by virtue of the individual's relationship with the organization and without regard to the accomplishment of exempt purposes.[113] Unlike in the private benefit analysis, inurement is not weighed against the public purpose served. Instead, there is an absolute prohibition on private inurement. In addition, inurement is a strictly economic concept. The inurement prohibition applies to persons in a

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[110] Inurement is a type of private benefit that is statutorily prohibited for Section 501(c)(3) organizations. The restriction on private benefit is found in the regulations and is based upon common law regarding charitable organizations, Treas. Reg. § 1.501(c)(3)-1(d)(1)(ii), which requires that the organization operate for public interest rather than for private benefit.

[111] See Rev. Rul. 70-186, 1970-1 C.B. 128.

[112] General Counsel Memorandum 39598 (1/23/87). In determining if the private benefit of a particular activity is outweighed by the public purpose, only the public benefit derived from that activity is considered, not the general public benefit provided by the exempt organization from all its activities.

[113] General Counsel Memorandum 38459 (7/31/80).

position of control or influence over all or part of a Section 501(c)(3) organization, i.e., "insiders." At one point in time, the IRS took the position that all physicians were insiders. However, Congress has clarified (and the IRS has conceded) that only persons who have control or substantial influence will be considered insiders.[114] Examples of private inurement include payment of excessive compensation or provision of below-market rent to insiders. It also encompasses the purchase of goods or services by a Section 501(c)(3) organization from an insider at above-market rates.[115]

3. ACO Participating Providers That Are Tax Exempt

Both the prohibition on private inurement and private benefit will be of importance if an ACO attempts to obtain or obtains Section 501(c)(3) status. Moreover, these same concerns must also be considered and analyzed in situations where Section 501(c)(3) provider organizations participate in or interact with a for-profit ACO.

If a tax-exempt entity participates in an ACO that is not a tax-exempt entity and it has a number of for-profit participants, there are a number of issues it should address. The primary concern of the participating tax-exempt organization will be protection and preservation of its tax-exempt status. Each participating tax-exempt entity should determine if participation in the ACO directly furthers its exempt purposes. If it does, exemption will not be jeopardized. In addition, although the language of Section 501(c)(3) requires an entity to be organized and operated "exclusively" for the purposes set forth in Section 501(c)(3), the test is actually a primary purposes test.

Joint ventures must be arranged to avoid private inurement and excessive private benefit. All participants in a joint venture should provide sufficient value to the venture in exchange for their ownership interest. Voting and dissolution rights should also be commensurate with ownership interests.

If the ACO is conducted in a pass-through entity, a pro rata portion of the activities of that entity will be attributed to the Section 501(c)(3) entity. If the ACO's activities are not substantially related to the Section 501(c)(3) entity's exempt purposes, the activities will be characterized as unrelated trade or business activities. In determining if a Section 501(c)(3) entity's status is jeopardized because it may be engaged in substantial unrelated activities, all unrelated trade or business activities of the entity must be aggregated. Although the analysis is commonly done by looking at the gross receipts generated by such activities compared to total receipts, it is also important to look at the amount of time and resources that the organization devotes to its unrelated trade or business activities compared to the total time and resources the organization devotes to all activities. Unfortunately, the IRS has never categorically stated that a certain percentage, in all circumstances, will jeopardize an entity's tax-exempt

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[114] H.R. Rep. No. 506, 104th Cong. 2d Sess. (1996) at 58, note 12.

[115] Joint ventures must also be analyzed to avoid prohibited private inurement or substantial private benefit, as discussed below.

status.[116]

Organizations need to periodically review the level of their unrelated trade or business activities. When unrelated trade or business receipts become too large of a percentage, organizations should consider moving those activities to a for-profit subsidiary. A good rule of thumb is to start reviewing options when unrelated trade or business activities reaches 15 percent to 20 percent of total receipts.

The IRS has an additional tool to ensure that financial arrangements between Section 501(c)(3) organizations and individuals or for-profit ventures are fair and reasonable. Code Section 4958 provides for the taxation of those persons who engage in impermissible private transactions with an applicable tax-exempt entity. The provisions of this Code section are commonly referred to as "excise taxes on excess benefit transactions" or "intermediate sanctions." Section 4958 applies to both Section 501(c)(3) and 501(c)(4)[117] organizations. An excess benefit transaction includes any transaction in which an economic benefit is provided by such an entity either directly or indirectly to a disqualified person that exceeds the value of the consideration received for providing the benefit. In addition, excess benefit transactions include any transaction in which the amount of any economic benefit is determined in whole or in part by the revenues of one or more activities of the organization, but only if the transaction results in impermissible private inurement. "Disqualified persons" include the following:

- Those persons who were, at any time during a five-year period ending on the date of the excess benefit transaction, in a position to exercise substantial influence over the affairs of the exempt organization[118]
- A member of such person's family
- Any entity in which such person or such person's family owns more than a 35-percent interest
- Any other person who may be a "disqualified person," depending on the facts and circumstances[119]

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[116] In one circumstance, the IRS ruled that an entity would retain its tax exemption where 75 percent of its gross revenues were generated by unrelated trade or business activities. Rev. Rul. 57-313, 1957-2 C.B. 316. However, in *Orange County Agricultural Society, Inc. v. Commissioner*, 893 F.2d 529 (2d Cir.1990), the court upheld the revocation of an entity's tax exemption where 29 percent in one year and 35 percent in the next year of total receipts were generated by unrelated trade or business activities. In this instance, the revocation was also based upon the alternative finding of private inurement.

[117] Section 501(c)(4) grants exemption to civic leagues or organizations operated for the promotion of social welfare. Contributions to Section 501(c)(4) entities are not deductible.

[118] Such persons include voting members of the governing body; regardless of title, anyone who has ultimate responsibility for implementing the decisions of the governing body or for supervising the management, administration or operation of the organization; and regardless of title, anyone who has ultimate responsibility for managing the finances of the organization.

[119] The following are examples of facts and circumstances tending to show that a person has "substantial influence" over the affairs of the organization: the person founded the organization; the person is a substantial contributor to the organization; the person's compensation is based primarily on

If an excess benefit transaction occurs, a tax will be imposed upon the person receiving the benefit.[120] In addition, a tax may be jointly and severally assessed against any of the organization's individuals (board members or officers) who approved or joined in the decision to participate in the excess benefit transaction.

The excess benefit provisions of Section 4958 do not prohibit transactions between a Section 501(c)(3) entity and a disqualified person. In order to avoid any penalties, the transaction must be on fair-market terms. In compensation arrangements, all economic benefits provided by the Section 501(c)(3) entity must be included in determining if total compensation is at fair-market rates. The best determinate of such fair-market rates is comparables. Since ACOs are relatively new, relevant comparables may be difficult to find.

The regulations under Section 4958 presume payments under a compensation arrangement are at fair-market rates, if the following three conditions are satisfied:

- The compensation arrangement is approved in advance by an authorized body composed entirely of individuals who do not have a conflict of interest with respect to the compensation arrangement[121]
- The authorized body obtained and relied upon appropriate comparables[122]
- The authorized body adequately documents the basis for its determination contemporaneously with making that determination[123]

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revenues derived from organization activities that the person controls; the person has or shares authority to control or determine a substantial portion of the organization's capital expenditures, operating budget or compensation for employees; the person manages a discrete segment or activity of the organization that represents a substantial portion of its activities, assets, income or expenses; the person owns a controlling interest in a corporation, partnership or trust that is a disqualified person; the person is a non-stock organization controlled directly or indirectly by one or more disqualified persons. The following are examples of factors tending to show that a person does not have substantial influence: the person has taken a bona fide vow of poverty as an employee or agent or on behalf of a religious organization; the person is an independent contractor whose sole relationship to the organization is providing professional advice and the person has no decision-making authority and will drive no direct or indirect benefit from the transaction except for customary fees for professional advice; the direct supervisor of the person is not a disqualified person; and the person does not participate in any management decisions affecting the organization as a whole or affecting a discrete segment of the organization that represents a substantial portion of its activities, assets, income, or expenses.

[120] The tax is equal to 25 percent of the excess benefit. It is an excise tax — in the nature of a penalty — and is not deductible for income tax purposes. The person receiving the benefit must "correct" the excess benefit by making the Section 501(c)(3) entity whole — usually by paying back the excess benefit with interest. No tax or penalty is imposed on the Section 501(c)(3) entity. However, individuals within the entity that are involved in the excess benefit transaction (or have approved it) may be jointly and severally subject to a penalty of 10 percent up to a maximum of $20,000.

[121] Treas. Reg. § 53.4958-5(a)(1).

[122] Treas. Reg. § 53.4958-5(a)(2). Since comparables may be difficult to find, a review by an independent consultant may provide the best support for fair market rates.

[123] Treas. Reg. § 53.4958-5(a)(3).

Since it may be difficult (at least in the early stages of ACOs) to provide relevant comparables, following the conditions for the rebuttable presumption will provide ACOs with a solid argument that the terms of the compensation are at fair market rates.

4. Tax-Exempt Bond Issues — Private Use Concerns

Tax-exempt organizations that have facilities financed with tax-exempt debt must also consider whether its involvement in an ACO constitutes "private use" under the rules prescribed under the Internal Revenue Code. In order not to jeopardize the tax-exempt nature of its bonds, a tax-exempt organization may only permit a small portion of its bond-financed facilities (generally less than 10 percent) to be "used" by private parties.[124]

If the arrangements with an ACO constitute a "management contract" under the private use provisions, the IRS has provided safe harbors that, if met, will not cause there to be bad use. A management contract is defined as "a management, service or incentive payment contact between a qualified user and a service provider under which the service provider provides services involving all, a portion of, or any function of, a facility."[125]

In order to fall within the safe harbors, the management contract must meet contracting standards developed by the IRS that set forth maximum terms of agreements dependent on the form of compensation payable to the service provider. In general, the more fixed and determinable the compensation, the longer the term of the agreement may be. In most circumstances, the tax-exempt organization must be able to cancel the contract without cause or penalty after only a year or two. Since the fallout from exceeding the bad use percentage can be catastrophic, tax-exempt entities will need to carefully analyze the ACO and any use that the ACO may have of tax-exempt bond financed facilities or equipment in order to protect the tax-exempt nature of its bonds.

5. Property Tax Issues

For most tax-exempt entities, the property tax exemption for real and personal property is a considerable savings. Most states that have an exemption also provide that if the property is used in unrelated trade or business activities or is used by an entity that would not, itself, be exempt from the property tax, that portion of the property so used will lose its tax-exempt status. Tax-exempt entities need to take this potential increase in

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[124] Private use means any direct or indirect use in a trade or business carried on by any person other than a governmental unit or other Section 501(c)(3) private entity that such use is a substantially related activity. Private business use can arise through ownership, actual or beneficial use pursuant to a lease, a management or incentive payment contract, or certain other arrangements determined by the IRS to constitute private use. Code § 141(b)(6)(A). Generally, there will be "too much" private use if more than 10 percent of the proceeds of the bond issue are to be used for any private business use. Costs of issuing the bonds are considered "bad use" and usually run about two percent to three percent of the bond issuance. Thus, the amount of permitted bad use is really no more than seven percent. All activities that create bad use must be aggregated when determining if this percentage is exceeded. See Rev. Proc. 97-13, 1997-1 C.B. 632, Section 2.01(3).

[125] Treas. Reg. § 1.141-3(b)(4)(ii).

costs into consideration when entering into an ACO arrangement if the ACO is not itself an exempt entity.

VI. MEETING THE ACO IMPLEMENTATION CHALLENGES: PREPARING FOR PARTICIPATION IN ACOS

Sections III, IV, and V of this white paper identify numerous challenges and issues that must be addressed for ACOs to realize the various goals proponents have identified for them. Perhaps it is because of these complicated financial, practical, technological, and legal issues that PPACA did not fully embrace and require implementation of ACOs.

As noted above, PPACA only took a transitional step of permitting ACOs to voluntarily participate in a shared savings or partial capitation program starting in January 2012. Otherwise, PPACA authorizes the Secretary of HHS to implement pilot and demonstration projects designed for voluntary participation by providers, including ACOs. The success of these pilot and demonstration programs may well determine whether, in what form, and how fast ACOs will become part of our health care delivery system.

A key question is what can or should providers and other participants in our health care system do now to help ready themselves to establish and implement an ACO in the next several years.

A. Unique Circumstances of the Provider

What any particular provider or other entity should do necessarily will depend upon who the provider or other entity is and the nature of its current and prospective relationships with other participants in its health care market. An IDS, a primary care clinic, a multi-specialty clinic, a small hospital system without employed or affiliated physicians, academic medical centers, and home care agencies will all need to assess their respective individual circumstances and situations. Each may be at very different stages of developing toward an accountable care capability and may need to take very different steps to prepare to become or participate in an ACO.

Each provider, supplier, and payor would be well advised to begin now to assess its individual circumstances and to determine what role it will want to play in an accountable care environment. Each entity will initially want to assess whether it has the necessary resources to form and lead an ACO or whether it is better positioned to join someone else's ACO through an affiliation or network participation agreement. A broad ACO covering services across the continuum of care and available throughout a broad geographic market is most likely to be successful. This white paper identifies issues that should be considered and addressed in the process of deciding whether to form or become part of an ACO — or not.

B. Aggressively Explore Alignments

All proposed ACO structures and payment arrangements require extensive provider alignment and coordination. Hospitals, physicians, and other providers will need to establish relationships through various organizational structures that permit them to work together effectively in a legally compliant manner to deliver on ACO goals. As noted above, IDSs, with their control over disparate types of providers, may be best suited to become ACOs. Community hospitals and other providers should focus on identifying what type of provider

network will be needed to best serve their local or regional markets and what legal and financial structures will most effectively support such a network. Understanding the local and regional market, and knowing the available provider resources and alliances in that market, will be important considerations in deciding how best to design and structure such ACO relationships. Each provider should ask itself whether it is equipped to be an ACO leader or whether it will need to seek to affiliate with a larger or stronger organization.

C. Ability to Assume Risk; Coordination of Care

Successful participation in an ACO is likely to require providers to take financial risk. History has shown that not all providers can do that successfully. In an environment in which providers assume financial risk, providers need tools to review and control costs and utilization in a timely manner and to deliver care in an efficient manner. Alignment with a broad array of providers and effective care coordination are not enough. Successful ACOs will need to have protocols for cost-effective care, clinical decision-support tools, and real-time utilization monitoring capability to be effective in controlling costs while delivering quality care. Payment incentives will be important if tied to use of these tools and to appropriate value-based behavior. Reinsurance and adequate capital and financial resources are also key preconditions to any decision to enter into a significant risk-sharing arrangement. Otherwise, the ACO may not be in a position to bear such financial risk.

D. Payment Structures

This white paper has discussed three principal payment methods likely to be utilized with ACOs: shared savings, bundled payment/episode-of-care, and capitation arrangements. ACOs will need to determine how to allocate payments to their participants in a fair and equitable manner and to use payments to align incentives for coordinating care among participants and across facilities and sites of care. If the ACO receives a bundled payment but pays its participants on a fee-for-service basis, the misalignment of incentives could lead to perverse economic and clinical results. Aligning such incentives among ACO participants will be challenging as both a practical and a legal matter. ACOs will need to consider and experiment with various payment arrangements that reward adherence to care protocols and achievement of quality and efficiency goals.

E. IT Systems

ACO participants will need to measure and monitor the quality and cost of care being provided by all of the ACO's participants, as well as out-of-network care, in a timely and accurate manner. Do providers have adequate IT systems for these purposes? If not, what is a strategy to ensure availability of the necessary IT infrastructure? Can the ACO afford it? Is government or payor funding available? Is private equity funding available? Does the technology allow the ACO to clinically integrate, coordinate care, and control costs in a manner that works? Is the right technology available yet at the right price? If not, when should such IT investments be made — and what should be done in the interim?

F. Human Resources and Support

One question an organization should ask itself is whether it has the administrative talent and resources to support an ACO. The administrative infrastructure needed to support an ACO may be very different from the workforce skills needed to run a hospital or medical group. ACOs may involve medical management, care coordination, contract administration, and payment processes that are alien to many provider organizations. Does the organization have the human resources to support these functions? Can it ramp up to do so? Can it afford to, in terms of both expense and management/organizational distraction? Can it afford not to?

G. Capital Access

As discussed above, ACOs will require significant capital for developing IT and administrative systems, expanding human resources, taking financial risks, and other ACO purposes. An organization seeking to operate an ACO should ask itself whether it has sufficient capital for such an ambitious undertaking and, if not, how it may go about obtaining it. ACO participants will want to ensure that their ACO is adequately capitalized to see it through the execution of its business plan.

H. Work With Third-Party Payors

Providers should approach third-party payors to judge their appetite for ACOs and to discuss whether and how the payors intend to support ACO development. If ACOs get too far ahead of payors, or if payors go in a different direction, costly midcourse adjustments may be needed down the line. Insurers and third-party payors will also likely be testing their own ideas about how ACOs should be paid to function best. Moreover, some insurers may have designs on becoming ACOs themselves, either through their own networks of participating providers or through staff model HMO arrangements. A collaborative discussion with the various payors to get their perspectives would be an advisable early step in planning an ACO project.

I. Participate in Demonstration and Pilot Programs

Providers seriously interested in forming an ACO should actively seek to take advantage of the planned ACO pilot projects and demonstration programs. Generally, providers may apply to participate in such programs, subject to the qualifications specified by CMS. Participation in these programs will permit providers an early opportunity to assess their readiness for ACO structures and payment methodologies, in part on the government's dime. They may also position the ACO for seed funding by the new CMMI. Participation may also provide some first-mover advantages and provide valuable lessons about best ACO business models and practices — that is, if the ACO plans carefully and avoids costly early mistakes.

VII. Conclusion

Proponents hold much hope that ACOs will change our health care system in a manner that will result in better-quality care while reducing health care costs. As discussed above, there are numerous challenges to be confronted, engaged in, and overcome for ACOs to fulfill that promise. Successfully achieving the goals for which ACOs are designed will take an intensive and probably long-term commitment from providers of all types, together with the government and private payors. ACOs may ultimately transform health care delivery and payment systems. But the industry is at the very threshold of this change. Courageous pioneering efforts will be needed to prove out the ACO proposition and guide the way to best ACO models and practices. Health care participants that are interested in joining this trailblazing effort should inform themselves of the challenges ahead and begin taking steps now to prepare for this perilous journey through uncharted territory. Getting to the destination may well be worth it, if at the end of the trail we find an economically sustainable health care delivery system to which all have access and that consistently delivers the best in evidence-based, cost-effective care.

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