American Hospital Association

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Submitted electronically via e-mail:
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September 27, 2010

Donald S. Clark, Secretary
The Federal Trade Commission
600 Pennsylvania Ave., NW
Washington, DC 20580

Daniel R. Levinson, Inspector General
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

Donald M. Berwick, MD, Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Ave., SW, Rm. 445-G
Washington, DC 20201

RE: Workshop regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, Civil Monetary Penalty (CMP) Laws

Dear Secretary Clark, Dr. Berwick and Inspector Levinson:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our nearly 40,000 individual members, the American Hospital Association (AHA) welcomes your decision to convene a workshop and to examine how your enforcement of the antitrust, physician self-referral, anti-kickback and civil monetary penalty laws will affect achievement of health care reform's goal of transforming the health care delivery system through the integrated delivery of care. As you point out in the *Federal Register* notice announcing the workshop, the *Patient Protection and Accountable Care Act* (ACA) "seeks to improve the quality of health care services and to lower health care costs by encouraging providers to create integrated health care delivery systems." While we understand your interest in the potential of accountable care organizations (ACOs), which are still undefined in regulation, we urge you to look more broadly at the impact your enforcement of these laws is having on the variety and spectrum of clinical integration activities that will be necessary to achieve the ACA's goals.

The AHA and its members have long advocated the benefits of coordinated care and sought ways to address the problems of a fragmented health care delivery system. Through its most recent initiative, *Health for Life: Better Health, Better Health Care*, the AHA offered a framework for change – a set of goals and ideas for creating better, safer, more affordable care

and a healthier America. A key component of that initiative was eliminating the legal and regulatory barriers to greater collaboration and teamwork between hospitals and other providers. We agree that how you enforce the laws on which this workshop focuses will be key to determining whether the clinical integration necessary to achieve the goals of health care reform will occur.

The AHA has done significant work examining the current impact of these laws on the ability of providers to work cooperatively to improve the quality and efficiency of the care they deliver to patients, and the serious impediments these laws create. We appreciate the opportunity to share what we have learned and look forward to working with you to achieve the necessary changes.

Since 2007, the AHA has urged the federal agencies to recognize the public policy imperatives for clinical integration and called for guidance and enforcement of the laws to enable hospitals and others to work together. The passage of health care reform makes the need for additional guidance and appropriate enforcement of these laws even more critical. Although CMS has yet to issue proposed regulations governing ACOs and bundled payments, or any of the other ACA initiatives designed to encourage clinical integration, hundreds of hospitals throughout the country have begun to consider ways that they can collaborate with physicians and other providers. A recurring concern in these planning discussions has been how to ensure that such efforts can withstand legal scrutiny.

Through the attached documents we hope to provide information about the landscape of clinical integration activity – what is being attempted or done, and what cannot be done – under the current legal regime, as well as a drill-down look at the individual laws, the impediments we have identified, and recommendations for the kind of changes that are needed.

The 2010 *Trendwatch* report, "Clinical Integration – The Key to Real Reform," examines how hospitals are working with physicians and other care providers to more closely coordinate care, and the legal and regulatory barriers to this critical element of health care reform. A chart at the end of the report summarizes which federal and state laws apply to clinical integration and the unintended consequences of their current application.

The 2010 *AHA Research Synthesis Report*, "Accountable Care Organizations," presents an overview of ACOs, including a discussion of their potential impact, key questions to consider in developing an ACO, and a review of the key competencies needed to be an effective ACO. The report is focused on the overall concept of ACO with highlights of the specifics of the ACO model proposed in health reform legislation.

The recently revised "Guidance for Clinical Integration," a working paper developed in 2007, was prepared for the AHA by a team of antitrust experts. It includes a road map for hospitals and other providers spelling out what they need to consider in establishing a clinical integration program, as well as a discussion aimed primarily at hospital counsel on some of the more difficult antitrust issues raised by such efforts. The AHA recognizes that considerable information has been provided in recent years by the FTC. What is missing, however, is user-friendly, officially backed guidance that clearly explains to caregivers what issues they must resolve to embark on a clinical integration program without violating the antitrust laws.

The set of fact sheets, "Getting More Reform from Health Reform: Five Barriers to Clinical Integration in Hospitals (and what to do about them)," describe, in summary form, how each of the four laws that are the subject of the workshop, as well as the Internal Revenue Code, create barriers to clinical integration – the foundation for achieving the goals of the ACA. The physician self-referral law is premised on compensation arrangements for services rendered, an "hours worked" approach, that is out of sync with clinical integration, where compensation is linked to the achievement of results or use of clinical protocols or best practices. Its regulations have become a tight web of confusing and changing requirements that place hospitals at risk for serious sanctions based on inadvertent or procedural violations.

The civil monetary penalty (CMP) law is a vestige of concerns in the 1980's that Medicare patients might not receive the same level of services as other patients after the prospective payment system was implemented. In today's environment, it is impeding clinical integration programs. While health reform is about encouraging the use of best practices and clinical protocols, using incentives to reward physicians for following best practices and protocols can be penalized under current enforcement of the CMP law. The antikickback law has been stretched to cover any financial relationship between a hospital and physician. The result is that rewards for a physician following best practices or evidence-based protocols could be construed as violating the statute. The ACA is driving providers to clinically integrate to serve Medicare beneficiaries. Regulatory oversight of financial relationships between hospitals and physicians must also change to enable the clinical integration that is essential to achieve ACA's goals.

Clinical integration is important. Meaningful health care reform, and the quality and efficiency improvements it promises, is built around the teamwork clinical integration creates. The AHA looks forward to working with the agencies to assure the legal and regulatory framework is in place to enable hospitals, physicians, and other providers, to work together so the full benefits of clinical integration are realized and the goals of health care reform are achieved.

If you have any questions, feel free to contact me at (202) 626-2336 or mhatton@aha.org.

Sincerely,

Melinda Reid Hatton
Senior Vice President and General Counsel

Attachments:
Trendwatch, "Clinical Integration – The Key to Real Reform"
AHA Research Synthesis Report, "Accountable Care Organizations"
"Guidance for Clinical Integration"
"Getting More Reform from Health Reform: Five Barriers to Clinical Integration in Hospitals (and what to do about them)"

Guidance for Clinical Integration

(Updated) Working Paper

September 2010

AHA Introduction

In 2007, the American Hospital Association (AHA) urged the Department of Justice's (DOJ) Antitrust Division and the Federal Trade Commission (FTC) to provide further guidance on clinical integration to address the uncertainty that many caregivers face when seeking to ensure that their collaborative activities are consistent with the antitrust laws. To prompt an open discussion of these issues, the AHA issued a "Working Paper" that included a road map for hospitals and other caregivers on what they need to consider in establishing a clinical integration program, as well as a discussion aimed primarily at hospital counsel on some of the more difficult antitrust issues raised by such efforts. An updated version of the Working Paper is attached to these comments.

The passage of health care reform makes the need for additional guidance even more imperative. Although the Centers for Medicare & Medicaid Services (CMS) has yet to issue proposed regulations on accountable care organizations, bundled payments, or any of the other initiatives to encourage clinical integration that are in the *Patient Protection and Accountable Care Act* (ACA), hundreds of hospitals throughout the country have begun to consider ways that they can collaborate with physicians and other caregivers and providers. A recurring concern in these planning discussions has been how to ensure that such efforts can withstand antitrust scrutiny. The AHA recognizes that considerable information has been provided in recent years. The published FTC staff advisory opinions on individual clinical integration programs can be helpful for those already knowledgeable about antitrust. However, they do not provide that much comfort for most of AHA's members, particularly because they are very fact dependent, and the process for obtaining an opinion is burdensome, time consuming and very expensive. Therefore, the AHA continues to urge the agencies to issue further guidance for providers, and suggests that a useful starting point is the attached Working Paper.

A substantial part of the AHA Working Paper, and much of the discussion about antitrust and clinical integration, has focused on what are the constituents of clinical integration, and when joint negotiations may commence. These are, of course, crucially important threshold questions for any planned clinical integration program. But given the tremendous incentives in health care reform and related market forces to achieve significant efficiencies and quality improvements, it is likely that there will be many collaborations that clearly reflect substantial clinical integration and for which joint negotiations are reasonably necessary for success. For these efforts, the greater antitrust uncertainty will be whether such collaborations might be considered anticompetitive under the rule of reason.

A rule of reason inquiry is, of course, highly fact dependent, and inevitably there will be situations in which an antitrust assessment would be required to determine whether the venture,

on balance, would have anticompetitive effects. Nevertheless, here too, the agencies can provide useful guidance on how they will make such assessments. It is also possible for the agencies to identify certain situations where it is implausible for the collaboration to have the market power to cause anticompetitive effects. "Safety zones" for such situations will provide assurance to those qualifying collaborations that they should have little concern about an antitrust challenge.

The AHA submits that the following principles should apply to any rule of reason assessment of a clinical integration program.

There is no basis for favoring financial integration over clinical integration. The distinction between clinical integration and financial integration is becoming increasingly blurred, as clinical integration programs inevitably require substantial financial investments, and many, if not most, include various financial penalties and incentives. Moreover, clinical integration is actually a more compelling objective than financial integration – it is aimed directly at improving care and lowering costs. In contrast, the internal financial arrangements among a group of individual providers are really of no public concern. In short, the analysis of a provider collaboration under the rule of reason should be guided by the same antitrust principles that apply to other competitor collaborations. Clinically integrated arrangements should not be viewed as inherently more suspect or more likely to cause competitive harm than those arrangements that rely exclusively on financial integration.

High market shares do not necessarily imply that a collaboration will be anticompetitive. Market shares are simply one tool among many to assess whether market participants possess market power. Defining relevant markets can be a very difficult and uncertain endeavor. This is especially likely with provider collaborations that will typically span many different types of health care providers and specialties, and therefore require multiple product and geographic market inquiries. Moreover, in many cases, even high market shares may not be problematic. This may occur, for example, where entry barriers are low, or a collaboration is non-exclusive and employs methods to reduce the risk of anticompetitive spillover. The agencies recognized these principles in the recently revised *Horizontal Merger Guidelines*, which give greater weight than prior guidelines to various types of evidence other than market shares, revise upwards the market share benchmarks, and emphasize that the benchmarks should not be viewed as providing a rigid screen.

Low market shares, however, can provide assurance that a collaboration will not exercise market power. The agencies have recognized this and have stated that, absent extraordinary circumstances, they will not challenge an exclusive physician network joint venture whose physician participants share substantial financial risk and constitute 20 percent or less of the physicians in each physician specialty with active hospital staff privileges who practice in the relevant geographic market. This safety zone is expanded to 30 percent for a non-exclusive physician network joint venture. As described below, this safety zone should be revised and expanded, but it and other safety zones illustrate how the agencies have employed market-share screens to provide guidance to the business community.

The agencies should affirmatively acknowledge the potential efficiencies from exclusive network arrangements. The agencies are correct in recognizing that a non-exclusive

network with a high market share poses less risk of anticompetitive effects than an exclusive network with a comparable share, because health plans are free to contract directly with the non-exclusive network members outside of the network arrangement. For this reason, the FTC has given favorable responses to Advisory Opinion requests involving proposed non-exclusive networks with market shares as high as 100 percent where the networks have shown the need for such a high level of participation and have instituted safeguards against anticompetitive spillover effects.

On the other hand, there is no reason for the agencies to favor non-exclusive networks over exclusive networks where the share of the network is so small that it will not be able to exercise market power. Indeed, in such circumstances, exclusive arrangements are likely to be *more* procompetitive since they may be better able to facilitate the creation of efficiencies and minimize the risk of free-riding. Unfortunately, the agencies' existing safety zone disfavors exclusive arrangements by limiting their market shares to 20 percent as opposed to 30 percent for non-exclusive arrangements. Moreover, the typical FTC consent in physician network cases has not allowed joint negotiations with an exclusive arrangement – no matter how small – without prior FTC approval. The agencies should explicitly acknowledge that exclusive provider collaborations can have substantial procompetitive benefits, and not disfavor such arrangements where they have low market shares.

The agencies should revise their safety zones for provider collaborations that are financially or clinically integrated. The existing safety zones are far too limited to address most of the clinical integration efforts now under consideration. For example, they would not cover a hospital/physician collaboration. Nor would they cover the large number of arrangements that would exceed the 20 percent/30 percent thresholds by even modest amounts in order to ensure a broad array of physician specialties. The safety zones should be expanded and refined as follows:

- **The safety zones should cover all provider collaborations – including those involving hospitals and other non-physician providers.** There is no justification to limiting the safety zones to *physician* network joint ventures – they should apply equally to collaborations involving hospitals, physicians, and other types of providers. Indeed, a principal goal of current clinical integration efforts is to increase collaboration among various types of providers, including hospitals and physicians; disqualifying such arrangements from safety zone treatment makes no sense.

- **The safety zone should cover clinically integrated as well as financially integrated arrangements.** There is no justification for treating financially and clinically integrated networks differently with respect to a safety zone where the providers' market share cannot plausibly raise market power concerns.

  In short, as long as a provider collaboration, through various forms of financial integration, clinical integration, or both, has shown that it warrants rule of reason treatment, then it should be eligible for a safety zone based on low market shares.

- **The safety zone for financially <u>or</u> clinically integrated provider collaborations should extend to either exclusive or non-exclusive arrangements that involve less than 35 percent of the providers in the relevant product and geographic markets.** The *Health Care Policy Statements* in Statement 7 establish a safety zone for joint purchasing arrangements where: (1) the arrangement accounts for less than 35 percent of the total sales of the purchased product or service in the market; and (2) the cost of the products and services purchased jointly accounts for less than 20 percent of the total revenues from all products or services sold by each competing participant in the joint purchasing arrangement.

  The agencies set the first prong of the joint purchasing safety zone at 35 percent because a joint purchasing arrangement with a lower market share is not likely to be able to set prices below a competitive level. For the same reason, a provider collaboration – whether exclusive or non-exclusive – with less than a 35 percent share is unlikely to be able to set prices above a competitive level. Moreover, there are compelling reasons to increase the current safety zones from 20 percent/30 percent because, in many markets, these thresholds are below what is realistically needed to provide a full panel of providers spanning a broad array of specialties. Similarly, the fact that a hospital with a market share of 20-35 percent participates in a provider collaboration should not disqualify it from the safety zone.

The agencies should reiterate that many arrangements that do not qualify for safety zone treatment may nevertheless be lawful. In many cases, provider collaborations for a variety of reasons will not meet the stringent safety zone tests – yet still be able to survive rule of reason scrutiny. Moreover, the most innovative and efficient arrangements are likely to expand and the antitrust laws should not stand in the way of natural growth by virtue of greater market acceptance. It is crucial, therefore, that the agencies clearly explain that the safety zones are simply conservative signposts that will give providers the assurance that, if they are met, they will survive a rule of reason inquiry – but that many arrangements that do not meet these stringent tests can still survive rule of reason review.

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Statement for the Record

of the

American Hospital Association

for the

Federal Trade Commission – Health and Human Services Workshop:

Accountable Care Organizations

HHS Panel: Implications to Physician Self-Referral,

Anti-Kickback and Civil Monetary Penalty

October 5, 2010

The following is the prepared statement of the American Hospital Association panel representative.

I'm Jonathan Diesenhaus, a partner at Hogan Lovells, participating on behalf of the American Hospital Association (AHA). The AHA and its more than 5,000 member hospitals, health systems and other health care organizations, and its nearly 40,000 individual members, appreciate the opportunity to be part of this workshop. All welcome your decision to take a combined look at how your enforcement of current law will affect the achievement of Congress' goals - to transform the health care delivery system through the integrated delivery of care.

Congress has laid down a major challenge to providers and the agencies to change the delivery system. Regardless of the acronym used for the future delivery system – the essentials will be the same: cooperation, coordination, integration across providers to improve care for all patients – beneficiaries and others. Providers will only be able to do that if the enforcement of current laws similarly recognizes that imperative. We agree that how you enforce the self-referral, antikickback, and civil monetary penalty laws (as well as how the antitrust laws and Internal Revenue Code are enforced) will largely determine the success of health care reform

The AHA appreciates the opportunity to share our assessment of current legal and regulatory impediments to achieving the goals of health reform. Its comment letter provides more detail on these regulatory and legal issues and its recommendations.

As a starting point, we urge you to look broadly at the impact of your enforcement of these laws on clinical integration activities. While we understand your interest in the potential of accountable care organizations (ACO), an ACO is still more an idea than a specific entity. It will, and should, evolve over time. To achieve the goals of health reform, a variety and continuum of clinical integration activities will be necessary.

We also urge you to make full use of the waiver authority granted by Congress to enable the field to essentially reinvent care delivery. Congress has set-the-table for CMS and OIG to exercise your oversight of providers to foster and not inhibit achieving the goals of reform. Protection is as essential to enable providers to take the first steps towards integration as it is for realizing the most complete and comprehensive integrated systems. The reality for providers is that the care systems they develop along their integration journey should be available to all patients. Protecting only arrangements involving Medicare patients or, more problematically, only Medicare patients considered part of an ACO, will constrain and even eliminate innovation. A multi-track system for care, akin to double-blind drug trials, is impractical and unfair to patients.

Congress' message to providers is clear - break down your silos and work together. The same applies for the agencies, if delivery reform is to be achieved. The self-referral, antikickback and CMP laws were based on the need to keep hospitals and physicians at arm's length, so nearly every financial relationship is viewed with suspicion – even if it's an incentive to spur teamwork and quality improvement. Under the new framework of health reform, hospitals and physicians, and other providers must work together, aligned through clinical data and financial incentive to work as a cohesive team. A new forward-thinking regulatory framework is required to achieve the goals of reform.

GUIDANCE
FOR
CLINICAL INTEGRATION

(Updated) Working Paper

Hogan Lovells for The American Hospital Association

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April 2007
Revised September 2010

AMERICAN HOSPITAL ASSOCIATION: MOVING FORWARD ON CLINICAL INTEGRATION GUIDANCE[1]

The American Hospital Association ("AHA") represents more than 5,000 member hospitals, health systems and other health care organizations, and nearly 40,000 individual members. In 2007, AHA initiated a project to provide better guidance to hospitals and other health care providers on establishing and implementing clinical integration ("CI") programs consistent with the antitrust laws. With this goal in mind, AHA developed the initial version of this working paper which it shared with the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ") (collectively the "Agencies") and AHA's members. The paper includes: (1) *Proposed Guidance on Establishing Clinical Integration Programs*, which is designed to provide a road map for hospitals and other providers on what they need to consider in establishing a CI program; and (2) *Proposed Legal Analysis* aimed primarily at counsel, which expands on the guidance that the Agencies have furnished and addresses some of the more difficult antitrust issues raised by CI programs.

AHA embarked on this project because it recognized the critical importance of clinical integration for efforts by health care providers to improve quality and efficiency. Developments since 2007 have underscored this importance. The Health Information Technology for Economic and Clinical Health ("HITECH") provisions that Congress enacted as part of the stimulus package in early 2009 committed billions of federal dollars to create incentives for providers to develop the health information technology infrastructure that is a key component of effective collaboration.[2] Even more significant are the provisions of the Patient Protection and Affordable Care Act ("The Affordable Care Act") that are aimed at fostering clinical integration. As CMS Administrator Donald Berwick has observed, "[t]he Affordable Care Act will help us pay for quality and outcomes, not volume, with innovative tools such as bundled payments, incentives for hospitals that prevent readmissions, and accountable care organizations in which health-care providers who work in teams deliver better care with lower costs."[3]

As a result, hospitals are now investing an unprecedented amount of effort in exploring a large variety of ways that they can work more closely with physicians and other providers. The need for clear guidance on how they accomplish such clinical integration consistent with antitrust and other laws has never been greater. This document has been prepared as one step in providing guidance to the hospital field on what issues should be considered as CI programs are developed. AHA looks forward to a continuing dialogue with the FTC and DOJ regarding the antitrust issues associated with CI programs, and how they can be addressed. AHA believes that it can provide valuable input from hospitals regarding how CI programs can be structured and implemented, outside of the context of ongoing investigations, and contribute to the Agencies' consideration of how the antitrust laws should be applied to such efforts.

In providing its *Proposed Guidance* and *Proposed Legal Analysis*, AHA recognizes that each CI program must be tailored to meet the needs and circumstances of the providers involved and community in which they operate, and that there is therefore no "one size fits all" CI program. Similarly, AHA appreciates that there is no simple checklist that can be followed which will guarantee that a proposed CI program will not raise any antitrust issues. Indeed, these materials are not intended to be definitive legal advice. As organizations begin the process of considering such programs, they should do so in consultation with counsel, bearing in mind that these programs also may implicate other areas of law, including tax exemption and

"fraud and abuse" laws.[4] Nor are these materials intended to create a self-regulatory scheme or any sort of immunity from antitrust scrutiny.

Instead, these materials are intended to foster discussion with the FTC and DOJ in the hope of providing useful guidance on what is involved in establishing a CI program – one that offers the benefit of collaboration across providers to ensure better, more coordinated delivery of health care services – and the type and level of antitrust scrutiny that should be applied to certain aspects of such programs. Both AHA and the Agencies can benefit from sharing information and ideas on these issues.

PART ONE: INTRODUCTION

A. The Need for Greater Collaboration Among Health Care Providers to Improve Quality and Efficiency

The need for greater collaboration among health care providers has never been more compelling. Persistent fragmentation contributes to gaps in quality and efficiency that adversely impact providers and their patients. AHA has long recognized the importance of collaboration in health care, particularly between hospitals and physicians. A 2005 AHA Task Force on Delivery System Fragmentation supported "the integration of clinical care across providers, across settings and over time" as an important strategy to foster collaboration and, consequently, to improve the quality and efficiency of care.[5] A recent AHA *Trendwatch* publication entitled "Clinical Integration – The Key to Real Reform"[6] highlighted the crucial role of clinical integration in achieving the kind of systemic change needed in how health care delivery system.

In health care, collaboration, quality and greater efficiency are inextricably related. Prominent health care leaders Denis Cortese and Robert Smoldt, respectively CEO and chief administrative officer with the Mayo Clinic, summarized it succinctly: "Physicians need hospitals; hospitals need physicians. And, most of all, patients need their providers to work together."[7] Such integration, they note, "will help us reach a common vision . . . [for] health care that is safe, efficient, timely, equitable, and patient centered."[8]

At the same time, health care providers are actively looking for strategies to address unhealthy and wasteful fragmentation, they also are under increasing pressure from others – government and private payers in particular – to improve efficiency and quality. The need for efficiency is longstanding. In a 2000 report, *To Err is Human: Building a Safer Health System*,[9] the IOM called for improvements in the way care is delivered and particularly stressed the importance of creating systems that support caregivers and minimize risk of errors. In its subsequent 2001 report, *Crossing the Quality Chasm: A New Health System for the 21st Century*,[10] the IOM challenged the adequacy and appropriateness of the current health care system to address all components of quality and meet the needs of all Americans. According to the report, a 21st Century system should provide care that is "evidence-based, patient-centered, and systems-oriented."[11]

A number of commentators, including the IOM, advocate linking provider payment to provider performance on quality measures, because such an approach is "one of several mutually reinforcing strategies that collectively could move the health care system toward providing better-quality care and improved outcomes."[12] Numerous pay-for-performance and incentive programs have been launched in the private sector in recent years, and such efforts also have been incorporated into Medicare payment systems for both hospitals and physicians. The Affordable Care Act is accelerating such efforts through provisions for accountable care organizations, incentives for hospitals to prevent readmissions, and demonstrations for innovative reimbursement approaches including bundled and episode-of-care payments. To be effective, such programs need to foster collaboration by aligning hospital and physician incentives, encouraging them to work toward the same goals of improving quality and patient safety, and providing effective and appropriate care to create better health outcomes.

Because hospitals provide the organized locus for so much health care and many already have installed health information systems, they have been a primary target for quality

improvement efforts. Thus, the Medicare program's principal consumer-focused quality initiative has focused on hospitals and has been developed in collaboration with the Hospital Quality Alliance ("HQA"). The HQA is a public-private collaboration established to promote reporting on hospital quality of care. The HQA consists of organizations that represent consumers, hospitals, doctors, employers, accrediting organizations, and federal agencies.[13]

Physicians face special challenges as they strive to improve performance. "Most physicians remain in solo or small group practices and have neither the capital nor organizational capacity to invest in health information systems, the implementation of care management protocols, or ongoing quality improvement initiatives."[14] Thus, it is unclear whether physicians in solo or small practices can devote the resources to even comply with the growing number of pay-for-performance programs.

One approach that some physicians have taken to improve their efficiency and quality is to merge their practices into much larger physician groups or to be acquired by hospitals or other entities. Another approach which could be attractive to the large numbers of physicians who wish to remain in small practices is to "clinically integrate" so that they can remain independent, but can work together in ways that enable them to reap many of the benefits of practicing as part of a larger group or in a hospital system.[15]

B. The Benefits of Clinical Integration

Clinical integration is attractive to health care providers because it is viewed as an effective remedy to fragmentation. In essence, clinical integration involves providers working together in an interdependent fashion so that they can pool infrastructure and resources, and develop, implement and monitor protocols, "best practices," and various other organized processes that can enable them to furnish higher quality care in a more efficient manner than they likely could achieve working independently. Such programs can enable primary care physicians ("PCPs") and specialists of all kinds to work more closely with each other in a coordinated fashion.

There are many benefits to a hospital, other providers and patients from implementing a CI program. They include:

- **Foster Collaboration to Improve Quality of Care.** Collaboration is particularly important in health care. Gaps in quality can more effectively be addressed by better coordination among providers. CI programs can allow providers to better align their efforts to improve quality and patient safety in line with the six aims outlined in the IOM's 2001 report on quality improvement strategies.[16]
- **Improve Quality and Efficiency for Independent Providers.** Independent providers who wish to continue to work in solo or small group practices, yet access the infrastructure, staff, economies of scale and scope, and "best practices" that clinically-integrated arrangements can provide, can enable them to significantly improve the quality and efficiency of their practices.
- **Enable providers to perform well in Pay-for-Performance and other public reporting initiatives.** There is an increasing emphasis on linking payment to performance on various quality and efficiency measures, and to use public reporting mechanisms to identify for patients, employers and health plans those providers who achieve high performance scores.[17]

Clinical integration efforts can enable providers to perform better in such initiatives. For hospitals, such programs can enable a hospital to attract more patients and increased reimbursement to reflect their higher quality.

- **Gain experience in forming provider organizations responsible for an entire episode of care or population of patients.** There is growing interest in both the public and private sectors to structure reimbursement systems based on provider organizations taking responsibility for the care of a population of patients, or for an episode of care.[18] Such provider organizations would need to span both hospitals and physicians practicing in a broad range of specialties. Clinically-integrated physician-hospital organizations can provide experience with, and form the basis of, such entities.

- **Provide a vehicle for a hospital to work more closely with members of its medical staff.** CI programs can provide a focal point around which hospitals can more closely associate with their physicians to build an integrated system of care. A CI program also can provide a hospital with many more monitoring and enforcement tools than are available to the hospital through a typical medical staff organization, including the payment of financial incentives for members who actively participate in the program and penalties for those who do not.

- **Provide the means whereby providers can obtain greater reimbursement to cover the added costs of their efforts and which recognize the increased value of the services that they offer.** A properly established and implemented CI program can justify joint negotiations by competing providers that would otherwise be unlawful under the antitrust laws. Such joint negotiations also can offer significant efficiencies for both providers and health plans in negotiating and administering contracts.

C. Hospitals Can Play a Unique Role in Clinical Integration Efforts

Hospitals are in a unique position to provide a focal point and leadership for CI programs. Hospitals already have access to the great majority of practicing physicians in the community. The average U.S. hospital has an extended medical staff of 88 physicians per hundred beds.[19] In fact, "virtually all physicians are either directly or indirectly affiliated with a local acute care hospital, whether through their own inpatient work or through the care patterns of the patients they serve."[20] Moreover, a medical staff provides a network of physicians who already are likely to be largely referring to each other, upon which further efforts can be built. Thus, a CI program can further reinforce the interdependence among the existing medical staff and can capitalize on and enhance these collaborative efforts. A CI program also can build on pre-existing hospital initiatives to improve quality and efficiency without "reinventing the wheel."

Typically, it is difficult for physicians to access capital required to invest in information technology ("IT"). Many hospitals have greater access to capital for investments in IT that gather information on and analyze physician practice patterns. Hospitals' ability to share IT with independent physicians, particularly electronic medical records ("EMRs"), has been greatly improved by recent regulatory changes to the Stark and anti-kickback laws.[21] Prior to those changes, those laws presented nearly insurmountable barriers to such an endeavor. The ability to share EMRs with physicians offers hospitals an unprecedented opportunity to employ

technology that better enables them to work together with physicians to improve the quality of care. Access to this type of technology, data and information, particularly when claims data are not available, can be important to the success of any CI program.

Moreover, hospital involvement ensures ready access to extensive information about hospital-based care. This information can be critical to the success of a CI program. It can be used to monitor the progress of the program, and to determine if providers are delivering consistent, higher quality services, which is the goal of any clinical integration initiative.

D. The Need for Greater Guidance on Clinical Integration

As discussed above, AHA views clinical integration as a means of ensuring better, more coordinated delivery of healthcare services. In an effort to ensure that its members are not inhibited in creating such programs due to antitrust concerns, AHA has also taken every opportunity to urge the antitrust authorities to provide concrete and practical guidance on the antitrust analysis of such ventures. AHA is not alone. A bipartisan group of twenty U.S. Senators have written Assistant Attorney General Varney and FTC Chairman Leibowitz urging them to provide more coherent guidance on clinical integration.[22] Indeed, the Agencies' Joint Report on Health Care referred to other commentators who have addressed the need for more Agency guidance.[23] In recognition of this void, the Agencies have asserted that they do not wish to "suggest particular structures" for clinical integration because it risks channeling market behavior, rather than encouraging market participants to develop their own structures.[24]

While AHA agrees that the Agencies should not channel behavior or dictate the precise details of a CI program, AHA believes that further guidance can be provided in a manner that would not do so. Further guidance is important because without it, providers may be discouraged from even attempting clinical integration efforts.

Part Two below, "*Proposed Guidance on Establishing Clinical Integration Programs*," is intended to fill this gap by providing a "road map" for providers on what they need to consider when creating a CI program.[25] This *Guidance* is not meant to suggest that it is the only path to clinical integration, because each program must be carefully adapted to fit the particular needs and circumstances of the providers involved. Nevertheless, the final goal is to provide concrete advice on the types of structures and processes that are likely to be evident in many successful clinical integration efforts. Of course, the *Guidance* is not intended to suggest that there be some sort of immunity for organizations that purport to follow the *Guidance*, but which have in fact taken few or no concrete steps to do so. As with any antitrust assessment, the crucial focus must be on substance over form.

Part Three below, "*Proposed Legal Analysis*," is intended to address some of the more difficult antitrust issues associated with CI programs, including the indicia of clinical integration, ancillarity, and competitive effects. It draws on well-established legal precedents, and is consistent with the Agencies' *Statements on Antitrust Enforcement Policy in Health Care*,[26] as well as the few FTC opinions issued in this area.

As noted in the *Proposed Legal Analysis*, CI programs in their infancy should not be judged in a manner that is overly static, nor should antitrust authorities attempt to substitute their judgment for that of medical experts. To do so could discourage innovation in its inception. Instead, CI programs should be viewed under the same legal precedents as any joint venture. When the potential for efficiencies exists, they should be evaluated under the rule of reason,

wherein their likely procompetitive benefits are weighed against the likelihood of harm to competition.

The time is ripe for many hospitals and physicians to create a new clinical enterprise that is built around alignment and commitment to care that is safe, timely, effective, efficient, equitable, and patient-centered. Not every hospital will look to clinical integration to accomplish these goals. But for those that do, it is important that legitimate efforts to fashion innovative and efficiency-enhancing methods for health care delivery not be discouraged by a lack of clear guidance. AHA hopes that this document will generate a dialogue with the Agencies that ultimately will furnish providers with concrete guidance that will encourage them to try innovative efforts such as clinical integration that hold the potential for reducing fragmentation and meeting the goals of 21st century health care.

PART TWO: PROPOSED GUIDANCE ON ESTABLISHING CLINICAL INTEGRATION PROGRAMS

There is, of course, no single approach that will fit all CI programs. Each effort will need to be carefully tailored to meet the needs and circumstances of the providers involved. Hospitals will vary with respect to the extent to which they have historically collaborated with their medical staffs, the interest of PCPs and specialists on the staff in joining a CI program, the size and sophistication of the physician groups, the amount of available IT and infrastructure already in place, access to claims data, the availability of knowledgeable physicians, nurses and other professionals who can take a lead in developing organizational processes, and a host of other factors.

Nevertheless, experience suggests that successful clinical integration efforts likely will need to take a number of similar steps and address many of the same issues in their development process. These are: (1) establish and articulate goals for the CI program; (2) selectively determine the CI program's clinical approach and participants; (3) develop mechanisms to monitor and control utilization of health care services and enhance quality and efficiency; (4) develop an infrastructure; and (5) determine when negotiations with payers can begin. These steps are described further below.

A. Establish and Articulate Goals for the CI Program

At the outset, the goals of the CI program should be clearly established and articulated. Among possible goals are the following:

- Improving quality and consistency of care
- Reducing costs and increasing efficiency
- Speeding adoption and common use of EMRs and other health IT
- Cost sharing for such improvements
- Reducing cost and burden of complying with health plan requirements such as pre-certification and utilization review
- Access to expertise, data and experience in negotiating contracts
- Enhanced reimbursement for providing higher quality care and/or for controlling the overall cost of care

The program should also carefully consider why collaboration is necessary to achieve the goals, and why the goals are more likely to be achieved through collaboration than through individual efforts. Some of the clinical goals may be similar to those that some selected individual providers might be able to achieve on their own. However, the CI program should hold the potential that more providers will achieve these goals, or achieve them more consistently or efficiently, than would be the case absent the joint effort.

Through the CI program, the providers will attempt to furnish higher quality care and/or reduce the overall cost of care. The overall cost of care is a function of both the price and the volume of care. The CI program can reduce the volume of care provided by keeping patients healthy, by reducing medical errors, and by minimizing the amount of inappropriate care given. Thus, higher fee schedules might not mean higher quality-adjusted prices for delivered health

care. Moreover, integration efforts are expensive, and experience shows that they will not be implemented without corresponding incentives. Thus, it is entirely reasonable for providers when embarking on a clinical integration effort to assume that they will need to negotiate together, and that such negotiations may result in higher fee schedules. On the other hand, providers should not view clinical integration simply as a means to justify joint negotiations that will enable them to raise prices.

Carefully considering and documenting the CI program's goals are important for two reasons. First, it ensures that there is a common understanding of the purposes of the endeavor, and therefore a secure foundation can be laid for further planning and implementation. Second, it helps to document the intention of the parties in the event of a subsequent antitrust review. While such a review will focus on the likely effects of the CI program, antitrust enforcers and the courts often look to contemporaneous documents to discern the parties' intentions on the assumption that these documents may shed light on the likely impact of the joint efforts.

B. Selectively Determine the Program's Clinical Approach and Participants

Determining what clinical conditions to cover and establishing clinical protocols and other organized processes for improving care. With its goals in mind, the program should consider the kinds of clinical conditions and services that will be covered and the range of processes it may wish to employ. Many programs are focused around a set of clinical protocols that are intended to establish "best practices" for treating or diagnosing a range of clinical conditions. Clinical protocols selected for use by providers can be "home-grown" to reflect local practice patterns, experience, and needs, or be built on evidence-based medicine and recommendations in the published medical literature. Regardless of which protocols are chosen, there must be a reasoned basis for the choice.

The identification of clinical protocols is only the first step. In addition, a program will need to identify an array of processes[27] and interventions designed to improve quality and efficiency; some of these might be related to the conditions covered by the protocols, while others could span a broad range of clinical conditions or a physician's entire practice. They might include, for example:

- Credentialing and re-credentialing
- Creation of disease registries
- Use of disease registries and other data to provide reminders for physicians and patients
- Programs to remind healthy patients about preventive care for which they are due (*e.g.*, mammograms, Pap smears, colon cancer screening)
- Nurse care management for patients with serious chronic illness
- Patient education programs
- Facilitation of EMR acquisition and of electronic communication among physician offices and between physicians and hospitals
- Programs to work with physicians' office staff to address questions and issues regarding payer requirements such as pre-certification and utilization review

A typical approach is for the staff employed by the CI program (or perhaps the hospital) to work with physicians in the organization who represent a range of specialties to determine which protocols and organized processes are likely to provide the best initial "return on investment." For example, protocols may be targeted in areas where the "best practices" have been well-documented and can provide significant quality and efficiency benefits, and where it is believed that there are the greatest opportunities for substantial improvement across the average participating provider. Protocols also may be chosen based on the measures that CMS and other payers are focusing on, or where there are opportunities for the hospital and physicians to earn increased reimbursement in pay-for-performance programs. Similarly, the program will need to identify what types of organized processes might be most practical and appropriate for the organization, and hold the greatest promise for getting results. The list of processes provided above is intended to give some sense of the kinds of initiatives that might be implemented, but the processes that the providers in an organization develop to work together to improve quality will be limited only by their own creativity and the resources at their disposal.

The choice of where to target the initial CI efforts will also depend on the availability of data. If the provider network already has capitated or other forms of risk contracts, it may have access to claims data that can be used to get a sense of how the physicians are performing for patients covered by these contracts, although such data may not provide clear insight into how care is being furnished to non-risk patients. Moreover, capitated contracts have become uncommon, and CI programs are likely to provide care predominantly or exclusively for patients covered by PPO or HMO non-capitated, fee-for-service contracts in which claims are submitted from, and paid directly to, the providers. In such situations, the CI program can try to obtain data directly from the payers, from the providers themselves as they submit their claims to the payers, or through electronic data clearinghouses that receive electronic claims from providers and transmit them to payers.

The hospital itself can be an excellent source of data regarding hospital-based care, including care furnished in hospital ambulatory settings. To the extent that claims data relevant to office-based care cannot be obtained, it may be necessary to employ nurses and other staff to perform office audits and chart reviews. These approaches can be very valuable, but are also very resource and time intensive. Office-based electronic medical records that can communicate with the organization's information systems can enhance and simplify this process, but at present only a minority of physician offices use EMRs.

Accordingly, many clinical integration efforts will start somewhat modestly, and expand over time as they develop data, infrastructure, processes and experience.

Once agreed upon, protocols and other organized processes must be disseminated to the participants in an organized, coherent, and useful fashion. This can be done through meetings and/or through paper or electronic communications. CI programs that have sophisticated IT systems can disseminate the protocols through their use.

Determine which providers will be included in the effort. By carefully selecting who can participate, a CI program can help assure minimum quality and efficiency standards and distinguish itself from others. CI programs that apply appropriately selective participation criteria tied to quality, cost-control and other efficiency measures present a very compelling case that their joint efforts have significant procompetitive potential.

When a CI program starts, it may need to employ relatively permissive selection criteria to ensure a full panel of providers. At the outset, the CI program may lack the necessary data to assess provider performance adequately, and substantial time and experience may be needed to gather and analyze the data to make rational and objective participation decisions. Moreover, the refusal to admit a provider to a network, particularly if it is a successful network, can be controversial. The expulsion of an existing member for failure to meet the CI program's efficiency standards is likely to be even more difficult. Therefore, some CI programs may have relatively relaxed participation criteria, at least at the beginning, but implement rigorous enforcement mechanisms to ensure that their members adhere to their standards, and gradually adapt more stringent participation requirements as they gain additional experience. In doing so, the CI program can adopt a range of interventions, including, for example, peer-to-peer counseling and other remediation activities that can be used before a decision is made to expel members.

Most clinical integration efforts will wish to encompass a broad range of physician services and specialties so that they can maximize the efficiencies that arise from the shared infrastructure and organized processes. A broad panel helps to assure that a wide range of clinical conditions can be handled, and patients can be certain that they will receive consistent care as suggested by the CI program's initiatives, even if they are referred across a wide range of specialists. A CI program's clinical initiatives, however, are not likely to have an equal impact on all providers. Some of them may be focused on PCPs, while others may address different specialties. As a result, the impact of a CI program likely will vary across type of clinician. To be viewed as active participants of a CI program, however, each physician should be subject to at least some of the initiatives and organized processes, with the expectation that they will be involved in an expanding number over time. Other CI programs may start out by focusing only on PCPs and focus all of their initiatives on PCP practices.

CI programs can raise antitrust concerns if they encompass a very large market share of the available providers. The federal antitrust Agencies have indicated that financially-integrated networks that are non-exclusive, and which encompass thirty percent or less of the physicians in each physician specialty with active hospital staff privileges in the relevant geographic market, are unlikely to raise significant antitrust issues.[28] While the Agencies have not addressed the question explicitly, such a threshold also should apply to a CI program. If a CI program wishes to include providers so that its market share would exceed this threshold, it still might be legal, but it raises more difficult questions that must be answered based on the particular market circumstances. Of course joint negotiations by programs that are neither financially- nor clinically-integrated run the risk of being considered *per se* illegal regardless of their market share.

Exclusivity. There are both potential benefits and concerns from exclusivity provisions whereby providers are available to payers only through a CI program.

Exclusivity assures the greatest commitment of the providers to the CI program and guards against free-riding by health plans, which may benefit from the enhanced efficiencies of the providers without having to pay for them. Thus, in certain respects, an exclusive CI program may hold the greatest potential for efficiencies.

On the other hand, exclusivity increases potential antitrust concerns because the participating providers are only available through the CI program. Such concerns, however, should be minimal where the CI program's market share is so low that it cannot plausibly have market power.[29]

Most CI programs are likely to be non-exclusive at the outset for practical reasons – they are unlikely to have enough clinically-integrated payer contracts to provide their members with a sufficient number of patients without also contracting with payers outside the CI program. Over time, however, some CI programs may seek to enhance their efficiencies by adopting a particularly rigorous set of initiatives with a more narrow provider network, and contract on an exclusive basis. If the CI program plans to operate on an exclusive basis, particularly if its market share in any specialty will arguably exceed 35 percent, it still may be legal, but further analysis will be needed to consider if the arrangement will likely be able to exercise market power to the detriment of consumers.

C. Develop Mechanisms to Monitor and Control Utilization of Health Care Services and Enhance Quality and Efficiency

A key component of most CI programs will be the gathering and monitoring of data regarding provider performance. Providers might receive feedback on how their performance has changed over time, how it compares to other providers in the CI program, or how it compares to external benchmarks, such as national or regional norms. There are advantages and disadvantages with each of these approaches.[30] Some measures may focus on process, that is whether the providers are performing certain procedures or taking specific steps that the medical literature or experience suggest are associated with better outcomes or lower costs. Alternatively, some measures may actually focus on outcomes themselves – that is, measuring the actual costs or clinical outcomes of the provider practices. Reliable outcomes measures, however, are the most difficult to obtain and interpret, because there are many variables that can explain patient outcomes other than physician performance, and it may be difficult or impossible to control for such variables. Again, there are advantages and disadvantages of each approach, and often a combination may be employed.[31]

Feedback can be provided in "report cards" that furnish useful comparative performance data. Such feedback, by itself, can often be very valuable in changing physician behavior. For example, merely learning that they are "outliers" on certain measures compared to colleagues who treat similar patients under similar conditions can cause clinicians to seriously reconsider their practice patterns.[32] "Peer-to-peer counseling" – having the medical director or other physicians in the program review the data with physicians who do not meet expectations – can be a powerful approach. It is also one which is not typically available to health plans, which may wish to achieve the same results, but do not have the local connection with, or often the same level of trust, of their participating physicians.

CI programs also may employ financial incentives to encourage improved performance. Performance may be measured on an individual level, on the level of a medical group within the organization, or the level of the entire organization (or some combination of the these). Measuring performance on the larger group level has the additional advantage of encouraging interdependence across the CI program participants. As with the report cards mentioned above, there are a range of options regarding which benchmarks should be used, and there are advantages and disadvantages of each approach.[33] Where payment for physician services goes directly from payers to physicians (for example, with a typical PPO or non-risk HMO contract), the program will need to work with payers, or otherwise develop other mechanisms, to capture a portion of payments to enable them to be redistributed based on the performance results.

Finally, CI programs may exclude from admission, or expel, providers who fail to meet certain performance standards. As with other initiatives, the ability and willingness to

limit membership likely will increase over time as the program and its members gain experience with the relevant criteria and performance measurement tools. And, as noted above, CI programs can take intermediate steps and work closely with providers so that they might be able to improve performance and avoid being expelled from the program.

A CI program can also go beyond monitoring performance, by providing tools and processes that help physicians improve the quality on a more efficient basis. For example, a program could send reminders and educational information to all women who should have yearly mammograms, but who have not had one in the past 18 months, or to diabetics who have not had a retinal exam in the past 18 months. The CI program has economies of scale to do this and is likely to be able to improve the screening rates for these and other things significantly without the need for physicians to "try harder" to remember to tell patients to do them.

D. Develop an Infrastructure

A successful CI program will require a substantial investment of both time and money. The most significant expenditures likely will be for a paid professional staff, including clinical and information systems personnel. Most CI programs find it is important to have a medical director, ideally full-time, but perhaps part-time for smaller organizations. Similarly, full- or part-time nurse care managers (depending on the size of the organization) to help coordinate the education and care of patients with severe chronic illnesses also may be important. In addition, clinically integrated organizations may have nurses and other professional staff who can review medical records, collect and analyze data, and interact with physicians and their professional staff.

Another significant item will be the development of an information system infrastructure, including both hardware and software, as well as hiring staff to implement the system on an ongoing basis, and educating providers and their staffs in the use of the information systems.

Also important will be the investment of time and cooperation by the providers. For example, physicians will need to work on quality improvement committees that might be expected to meet on a regular basis; some of these physicians might volunteer their time, while in other situations they might be paid. It can be very difficult to change provider practice patterns, and changes will not result from simply adopting a set of clinical guidelines and state-of-the-art IT. Rather, the CI program must obtain provider cooperation, which can be achieved only through providers working together and with the organization's staff, so that they understand the CI program's goals.

In CI programs involving both hospitals and physicians, a large majority of the costs of the collaboration are likely to be borne by the hospitals, at least in the early years of the organization's existence. Hospitals often have more ready access to significant financial resources, and may already be employing staff and creating an IT infrastructure that can be adapted to the CI program.

E. Determine When Negotiations with Payers Can Begin

Joint negotiations with payers can commence once the CI program can demonstrate that a degree of collaboration among its members has begun, and thus it is

integrated. This can be established, for example, if the CI program has begun by choosing protocols and implementing some organizational processes. Typically, the program also will be collecting its baseline data that will form the foundation for its feedback and enforcement mechanisms. At this early point, the program may not have actually obtained and analyzed all of the initial data, which can take some time, but it at least will be well on the way to gathering it and progressing down a well-conceived path involving the various components mentioned above. And, of course, as the CI program continues, and enters into joint negotiations with payers, it also must continue to make progress in the implementation of its initiatives. In other words, a good start does not immunize a program indefinitely, it merely ensures that there will not be summary antitrust condemnation.[34]

Questions may arise concerning the propriety of hospital staff participation in negotiations regarding physician fee schedules for those in the CI program. Such participation should not raise antitrust concerns if the hospital does not employ physicians who compete, or itself does not compete, with physicians who are in the CI program. Even if the hospital or its employed physicians do compete with physicians in the program, the hospital should still be permitted to participate in the negotiations if it and its employed physicians are actively participating in the clinical integration initiatives.

The hospital and physicians in the CI program may wish to jointly negotiate with health plans regarding both hospital and physician fee schedules at the same time as part of the same set of negotiations. There should be little antitrust risk in such efforts if: (a) neither the hospital nor the physicians have market power in the relevant market; (b) the health plan is given the option of having totally separate negotiations with the hospital or physician venture; or (c) the health care services delivered by the hospital and physicians through the CI program can be considered to be a single, integrated product. These can be complex questions, however, and the answers will depend on the particular circumstances and market conditions.

PART THREE: PROPOSED LEGAL ANALYSIS

The antitrust analysis of CI programs is grounded in well-established antitrust principles: agreements – including those affecting price – are analyzed under the rule of reason if they are reasonably necessary (*i.e.*, "ancillary") to an efficiency-enhancing joint venture.[35] The logic behind such principles is unassailable. *Per se* condemnation is reserved for only those "naked restraints" that always, or almost always, harm competition.[36] In contrast, where a venture has the potential to create efficiencies, it is not appropriate to summarily condemn the venture or the agreements that are ancillary to achieving its goals. Rather, the competitive effects of the arrangement must be analyzed under the rule of reason.

Nevertheless, there is some uncertainty concerning how these principles should be applied to the specific fact scenarios that arise when health care providers engage in collaborative efforts. In their 1996 revisions to the *Statements of Antitrust Enforcement Policy in Health Care ("Health Care Policy Statements" or "Statements")*[37] the Agencies provided some general guidance on clinical integration. But the Agencies have stated that they have been reluctant to be more specific lest they channel market behavior towards certain specific structures "rather than encourage market participants to develop structures responsive to their particular efficiency goals and the market conditions they favor."[38]

The Agencies are correct in acknowledging that there are many different approaches to achieving efficiencies, and that it is much preferable for health care providers to determine what approaches work for them, rather than model their programs on the pronouncements of antitrust enforcers. However, the absence of more specific guidance can have the unintended result of causing providers to be reluctant to move forward with clinical integration efforts out of uncertainty as to how these actions might be viewed under the antitrust laws.

AHA's *Proposed Guidance on Establishing Clinical Integration Programs* and this *Legal Analysis* are intended to fill some of the gaps by expanding on the guidance that the Agencies have furnished, and addressing some of the questions that frequently arise with clinical integration efforts. This *Proposed Legal Analysis* is divided into three parts. The first addresses how to determine whether a CI program is likely to produce significant efficiencies that benefit consumers. The second part discusses when joint negotiations may be reasonably necessary, or ancillary, to the collaboration. Finally, we discuss several issues that may arise in considering competitive effects under a rule of reason analysis.

A. Indicia of Clinical Integration

The threshold question in considering whether a collaboration avoids *per se* condemnation is whether or not it has the *potential* to create efficiencies.[39] The reason for focusing on the *potential* is that many joint ventures, like many efforts by fully-integrated merged entities, are not successful at creating all of the efficiencies they seek to achieve. Whether it is a research joint venture designed to develop a new drug or a CI program to enable health care providers to improve health care quality and efficiency, a requirement that the collaboration *must* prove successful in every way would deter innovation. Parties will be reluctant to embark on joint venture activities if they risk later *per se* condemnation in the event that the venture fails to achieve its goals.

Furthermore, whether a collaboration is the only way that such efficiencies can be produced or whether some might believe that the venture is not taking the optimal path to

achieve goals should *not* be the test under which the venture is judged. Often it is not clear – even among experts in the field – what is the most appropriate way to achieve efficiencies, let alone effectively test them. Perhaps nowhere is this as true as in health care.[40]

Thus, the focus of the inquiry must be on whether the CI program has developed the type of structure and processes that have the *potential* to produce efficiencies. Statement 8 of the *Health Care Policy Statements* states that the Agencies will assess "a network's *likelihood* of producing significant efficiencies."[41] One way, but not the only way, to demonstrate this likelihood is by the implementation of "an active and ongoing program to evaluate and modify practice patterns by the network's physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality."[42]

The AHA *Guidance on Establishing Clinical Integration Programs* is largely based on the *Health Care Policy Statements* and is an attempt to further clarify the *Statements'* articulated components and provide concrete, practical guidance that is useful to providers. The *Statements* provide that such a program may – but need not necessarily – include the following components:

- Selectively choosing program physicians who are likely to further the program's efficiency objectives;
- Establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care; and
- Significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.[43]

Of course, a provider network need not have these all of these components to be clinically integrated. Indeed, the mechanisms might very well be somewhat different when, for example, the CI program involves hospitals and hospital-employed physicians, rather than just independent physicians. Nevertheless, because of the prominence given to them in the *Health Care Policy Statements*, these indicia warrant further comment.

Selectively choosing participating providers to further the program's goals. By carefully selecting who can participate, a CI program can help assure minimum quality and efficiency standards and distinguish itself from others. CI programs that apply extremely selective participation criteria tied to quality, cost-control, and other efficiency measures present a very compelling case that their joint efforts have significant procompetitive potential.

On the other hand, although the *Health Care Policy Statements* refer to this factor, the absence of rigorous selection criteria, particularly in the early stages of a CI program, should not necessarily mean that the program lacks clinical integration. When a CI program starts, it may need to employ relatively permissive selection criteria to ensure a full panel of providers. Moreover, the CI program may lack the necessary data to assess provider performance adequately, and substantial time and experience may be needed to gather and analyze the data necessary for making rational and objective participation decisions. Finally, excluding a provider from a CI program, particularly if it is a successful program, can be controversial. Expulsion of an existing member for failure to meet the program's efficiency standards is likely to be even more difficult. Therefore, some CI programs may have less stringent participation criteria, at least at the beginning, but implement rigorous enforcement mechanisms to ensure that their members adhere to their standards, and gradually adopt more stringent participation requirements as they gain additional experience.[44] CI programs also may use a number of intermediate tools,

such as working with physicians on a "peer-to-peer counseling" basis to help them improve performance, or putting physicians who are failing to follow the CI program's initiatives in a provisional status before they are actually expelled from membership.

Developing mechanisms to monitor and control utilization of health care services and enhance quality. At the heart of clinical integration efforts are likely to be the actual mechanisms that are designed to control costs and assure quality of care. These mechanisms are meant to ensure collaboration and interdependence among participants. Elsewhere, such mechanisms have been called "organized processes."[45]

These mechanisms typically will involve the dissemination of clinical protocols, the collection and analysis of data regarding the participating providers' performance, and a process for providing feedback to the providers, perhaps with incentives or penalties based on that performance. But these efforts can go beyond monitoring performance, by providing tools and processes that help physicians improve their quality on a more efficient basis. For example, an organization could send reminders and education information to all women who should be having yearly mammograms who have not had one in the past 18 months, or to diabetics who have not had a retinal exam in the past 18 months. The organization has economies of scale to do this and is likely to be able to improve the screening rates for these and other things significantly, without the need for physicians to "try harder" to remember to tell patients to do them.[46]

There should be reasonable expectations concerning the breadth, scope, and number of processes and mechanisms that are employed. This includes the number and range of clinical protocols, the extent of the performance information that is gathered, and the enforcement mechanisms and incentives that are employed. It is important to recognize that establishing, implementing, and growing a CI program takes substantial time, effort, and resources. One should expect a program to begin with a set of initiatives that is significant, but which can still grow and evolve as it gains experience over time.[47] Thus, it is expected that programs likely will be more modest in their beginning stages than programs that have been in place for a number of years.

As noted in the AHA *Guidance on Establishing Clinical Integration Programs,* clinical protocols selected for use by providers can be "home-grown" to reflect local practice patterns, experience, and needs, or be built on evidence-based medicine and recommendations in the published medical literature. The key issue is not what protocols have been chosen or what specific mechanisms are used, but rather whether there is a reasoned basis for the choice, and whether efforts are being made on a continual basis to evaluate and take steps to improve their effectiveness.

Accordingly, while the Agencies should be expected to verify the fundamental characteristics of the CI program, they should not "second-guess" the specific medical approaches the CI program is taking. In short, the Agencies will seek to substantiate the processes utilized, but will not substitute their judgment on medical matters for those of practitioners.

The CI program may be able to obtain access to some claims data. This is common where the provider network also has capitated contracts for which it must process claims. Increasingly, however, provider networks are finding that most of their members are contracted to provide services under PPO or non-capitated HMO arrangements. In these situations, the CI program may seek access to submitted claims

either from health plans, directly from its participating physicians, or from electronic data clearinghouses that help in transmitting electronic claims to payers; such efforts, however, may be difficult to implement. Where a hospital is working with the CI program, it may be able to provide access to data about physician practices in the hospital setting (including ambulatory care furnished in hospital-affiliated entities). This can be a very important source of data related to services with the most significant cost and quality implications. Other sources of data could include chart reviews, patient registries related to specific clinical conditions, and visits to physician offices. Such efforts, however, can be very labor intensive and costly.

A key component of most CI programs will be the gathering and monitoring of data regarding provider performance. Providers might receive feedback on how their performance has changed over time or how they compare to other providers in the program or to external benchmarks. Such feedback can be provided in "report cards" that furnish useful comparative performance data. CI programs also may employ financial incentives to encourage improved performance. CI programs may exclude from admission, or expel, providers who fail to meet certain performance standards. As with other initiatives, the ability and willingness to limit membership likely will increase over time as the program and its members gain experience with the relevant criteria and performance measurement tools.

There are a large varieties of ways that CI programs may use to incentivize or penalize their members based on performance. Such incentives are used both to encourage certain improvements, as well as to compensate physicians for extra time and effort that otherwise might not be reimbursed. Provider performance may be measured against the providers' own historic performance, against the performance of others in the program, or against an external benchmark. There are advantages and disadvantages with each of these approaches.[48] Similarly, some measures may focus on process, that is whether the providers are performing certain procedures or taking specific steps that the medical literature or experience suggest are associated with better outcomes or lower costs. Alternatively, some measures may actually focus on outcomes themselves – that is, measuring the actual costs or clinical outcomes of the provider practices. Again, there are advantages and disadvantages to each approach, and often a combination may be employed.[49] Performance may be measured on an individual level, on the level of a medical group, on a larger collection of providers, or some combination of these. Where performance is measured on a group level, so that incentives or penalties are based on group performance, there is evidence of a degree of financial integration.

The test of whether a CI program has sufficient clinical integration to avoid *per se* treatment should not rest on the extent to which the program can demonstrate concrete improvements in quality or cost. For several reasons, such assessments are intrinsically very difficult, if not impossible, to make, and would put an unreasonable burden on the program.[50] First, quality and cost data mean little if they are not risk-adjusted for patient health, and perhaps their socioeconomic status as well. Such risk adjustment is very difficult to do. As a result, an organization may be providing very high quality care, but score poorly (for example, because its reputation or that of its providers attract sicker patients), and vice versa. Second, even if risk adjustment is plausible, it is difficult to determine what the appropriate benchmark might be. Because there are such substantial variations in care across regions, national norms may not be very useful, yet regional data are likely to be unavailable. Third, some improvements in care (particularly preventative care) may result in higher costs in the short term, and even in the long term if people live longer and incur medical expenses for a longer time.[51]

Moreover, as discussed above, the relevant legal issue for application of the *per se* rule is whether the CI program has the *potential* for efficiencies, not whether it has actually achieved such efficiencies. Many mergers and other fully-integrated joint ventures do not meet their initial expectations, but nevertheless are not subject to *per se* condemnation. But performance is relevant in two respects. First, a legitimate CI program can be expected to try to improve its performance by making its own self-evaluations, and where it is coming up short, taking steps to modify its own initiatives. Indeed, such ongoing self-assessments and modifications would be evidence that the CI program is seeking to create efficiencies and warrants rule of reason treatment. Second, the extent to which the CI program is able to achieve efficiencies is relevant to the analysis of competitive effects under the rule of reason.

Significant investment in infrastructure, including both human and monetary capital, to achieve claimed efficiencies. A successful CI program typically will require a substantial investment in both time and money. The most significant expenditures likely will be for a paid professional staff, including clinical and information systems personnel, as well as for an information system infrastructure, including both hardware and software. Also important will be the investment of time and commitment by the providers. Changing provider practice patterns can be a very difficult task, and will not result from simple adoption of a set of clinical guidelines and state-of-the-art IT. Rather, the CI program must obtain provider cooperation, which can be achieved only through working with providers, so that they understand the program's goals and programs.

In CI programs involving both hospitals and physicians, a large majority of the costs of the program may be borne by the hospitals. Hospitals often have more ready access to significant financial resources, and may already be employing staff and creating an IT infrastructure that can be adopted to the CI program. The source of the infrastructure funding is irrelevant, however, to addressing the antitrust issue of whether the program has the type of infrastructure that suggests it has the potential to create efficiencies.

Of course, to the extent that providers are sharing significantly in the investments needed for the infrastructure to produce efficiencies, that would constitute indicia of *financial* integration that would provide additional grounds for concluding that the CI program should receive rule of reason treatment.

Determining when the CI program is sufficiently established to begin joint negotiations. It can be difficult to determine when a CI program is sufficiently established so that it can jointly negotiate with payers for non-risk contracts, and the answer will vary depending on the type of collaboration. Generally, the CI program should not engage in joint negotiations until its infrastructure has been assembled and its program is established and ongoing. As noted in the AHA *Guidance*, a good rule of thumb for such efforts may be whether the program's organized processes are in place and data are being collected to determine a baseline against which the program's progress can be judged.

As discussed in detail below, if the joint negotiations are reasonably necessary to the success of the clinical integration, too long a delay could undercut the

endeavor. Providers will be reluctant to make extensive time and money commitments without assurances that they will reap some of the rewards of their collaboration in the foreseeable future. Furthermore, in some situations, the CI program may depend on active interaction with payers, including access to data that only health plans can provide. Thus, collective discussions with health plans about their willingness to work with the physician network on a clinically-integrated basis may be needed to get the program off the ground.

Clinical integration involving hospitals. The discussion above, and most of the Agencies' enforcement agenda, has been focused on clinical integration involving independent physicians. This is very relevant to many hospitals that wish to collaborate with their medical staff, or a subset of their medical staff, through a physician-hospital organization that would involve a collaboration spanning both hospital and physician services, and likely would entail the joint negotiation of fees that apply to the independent physicians.

Clinical integration also may apply to joint efforts by hospitals themselves to improve quality or reduce costs. In these efforts, the hospitals might work together to develop common protocols, shared services, monitoring and enforcement mechanisms, and other tools that enable them to create efficiencies that they could not achieve on their own. The principles discussed in this paper would apply equally to such efforts. Thus, collaborations across hospitals, or across several physician-hospital organizations (that is, a "super-PHO") could involve clinical integration to the extent that the providers are working in an interdependent fashion across the various organizations in ways that have the potential to create efficiencies beyond what the organizations might achieve on their own.

While clinical integration efforts across independent hospitals or hospital systems have been relatively rare so far, they have the potential of creating significant efficiencies. For example, they may be particularly valuable where physicians have staff privileges at multiple hospitals. By working together in a single clinically-integrated organization, these hospitals can help ensure that the participating physicians are subject to a single, consistent set of initiatives and incentives – which can increase their effectiveness. Even if physicians primarily practice in only one hospital or hospital system, or are hospital employees, efforts across hospitals can help raise the community-wide standard of care. Such initiatives across providers can be particularly valuable in connection with preventative care programs that can span a broad spectrum of providers and settings.

FTC staff has observed that such efforts by hospitals have the potential to create efficiencies. In its *Suburban Health Organization* Advisory Opinion,[52] FTC staff acknowledged that in a "super PHO" network composed of eight independent hospitals and 192 primary care physicians that were employed by them, a number of joint activities that the hospitals were undertaking had the potential to create some efficiencies. Although FTC staff ultimately found that the potential efficiencies of a "Super PHO" network could be achieved by individual hospitals on their own, the FTC staff appropriately applied a rule of reason analysis.

Market shares. As described above, the first step in assessing a competitor collaboration such as a CI program is to determine whether the joint venture offers sufficient potential for efficiencies so that an otherwise *per se* unlawful agreement, ancillary to that venture, warrants rule of reason treatment. Only then is further inquiry necessary to determine whether the venture will have market power and, thus, will likely result in anticompetitive effects.[53]

Under this scenario, therefore, the market share of the CI program should not be relevant to the initial determination of whether the program should be condemned as a *per se* price-fixing arrangement. While this is technically true, as a practical matter the antitrust risks posed by a CI program are related to its share of a properly defined market and whether it can exercise market power. Thus, for example, the Agencies in the *Competitive Collaboration Guidelines,* have established a safety zone for joint ventures that account for less than twenty percent of each relevant market in which competition might be affected.[54] This safety zone is also recognized as part of the Agencies' *Health Care Policy Statements*. Of course, a number of difficult questions can arise when determining the appropriate product and geographic markets for provider services. Moreover, to consider whether the program has market power, an assessment will need to be made regarding the likelihood of timely and sufficient entry.

Nevertheless, a less rigorous analysis may be appropriate in considering certain CI programs which, on their face, are unlikely to have market power. Thus, for example, a program that comprises less than 35 percent of physicians in all of the key specialties in the likely geographic market holds little prospect of having an anticompetitive effect. Although this does not give its members a free pass to engage in *per se* illegal conduct, it does suggest that both the intent, and effect, of the program will not be anticompetitive. In such cases, it would serve little purpose to investigate, or challenge, a program that has a plausible case that its activities will create efficiencies. [55] On the other hand, a program with a substantially larger share may hold a much greater risk of anticompetitive effects.

B. Relationship of Joint Contracting to Production of Efficiencies

Background. Under antitrust precedents, joint negotiations must be "ancillary" to the clinical integration to avoid *per se* condemnation.[56] The Agencies have described the applicable test as being whether the negotiations are "reasonably necessary" to a venture's efficiency-enhancing effects.[57] But it is clear that a "reasonably necessary" restraint need not be "essential" to the achievement of efficiencies. Rather, as Judge Posner explained in *General Leaseways, Inc. v. Nat'l Trucking Leasing Assoc*., 744 F.2d 588, 595 (7th Cir. 1984), there merely must be an "organic connection between the restraint and the cooperative needs of the enterprise that would allow us to call the restraint . . . ancillary." Similarly, as Judge Easterbrook has observed, "[a] restraint is ancillary when it may contribute to the success of a cooperative venture that promises greater productivity and output . . . If the restraint, viewed at the time it was adopted, may promote the success of this more extensive cooperation, then the court must scrutinize things carefully under the rule of reason."[58]

The FTC and DOJ, in their *Competitor Collaboration Guidelines*, state that they will conclude that the relevant agreement is not "reasonably necessary" if the participants could have achieved similar efficiencies by practical, significantly less restrictive means.[59] They note, however, that "[i]n making this assessment, the Agencies consider only alternatives that are practical in the business situation faced by the participants; the Agencies do not search for a theoretically less restrictive alternative that is not realistic given business realities."[60] For example, the Agencies observe that a restraint may be reasonably necessary to dissuade opportunistic conduct, such as free-riding by individual venture participants, or it may be necessary to discourage one participant from appropriating an undue share of the fruits of the collaboration or to align participant incentives to encourage cooperation in achieving the efficiency goals of the venture.[61] It is important that the Agencies do not require a showing that the agreement at issue is "essential" in an absolute sense. This is consistent with the relevant case law referenced above. It also reflects an appreciation of the dangers of reliance on theoretically less restrictive alternatives that, as a practical matter, do not reflect business realities.

Rationales for joint contracting. There are several reasons why joint pricing may be ancillary in a CI program. First, for a CI program to be effective, it must be able to count on the active participation of all of the group's members.[62] This cannot be guaranteed without collective negotiations that would assure that, if an agreement is reached with a payer, all of the program's physicians would participate. Thus, there may be a need for an agreement that if the payer's contracts satisfy certain price and non-price criteria, all of the program's physicians will participate.

Second, the CI program may wish to allocate revenues achieved from contracts in a way that provides incentives for physicians to make the investments in time and effort to develop and implement the program to meet the program's goals.[63] This may involve negotiating contracts in a way that provides greater compensation to some of the program participants, and less compensation to others, both to ensure participation of a broad provider network and to allocate revenues fairly based on the contributions and efforts made by the participants in implementing the program. In some cases, the program also may wish to implement financial rewards and penalties as part of an enforcement mechanism, and joint contract negotiations will be needed for such an effort.

Third, joint negotiations may be necessary to guard against the possibility of "free-riding" by certain physician members. The concern is that unless the program can negotiate and contract on behalf of all of its members, some physicians could free ride on the contributions of their colleagues and the accomplishments of the program, so that they can offer more efficient, higher quality services, and then contract independently to provide these services at a lower price by undercutting other program members. If this can occur, physicians may be reluctant to fully commit themselves to the program at the outset, thereby limiting the potential of the program.

Fourth, collective negotiations may be necessary to assure the active and ongoing participation of the physician members. CI programs require substantial commitments in both time and money by network providers. Without the joint

negotiation that can help them recover these costs, many providers might be unwilling to participate in the CI program in the first place. Therefore, such price agreements can be viewed as reasonably necessary for the success of the program.

Fifth, joint contracting can achieve transactional efficiencies in contract negotiation and administrative. As the FTC notes in its TriState Advisory Opinion, while these on their own may not be sufficient to offset the loss of competition from joint contracting, these type of efficiencies are cognizable.[64]

Finally, by implementing a CI program, the providers can sell a new and different product – that is, an integrated package consisting of more than merely the individual provider services, but, rather, an integrated package of those services tied to the CI program. In most programs, the services are integrated through the coordination of the providers in the program, by a dedicated staff, through the use of commonly agreed upon and enforced clinical protocols, the employment of various monitoring and enforcement mechanisms, and perhaps the sharing of clinical and other data through a shared IT system. This entire package could not be offered by providers individually. Nor would it be practical to deconstruct the package into many products – *e.g.*, performance measurement; feedback; and peer counseling; reminders for physicians and for patients; nurse care management for chronically severely ill patients; clinical protocols, and use of registries. It would be very cumbersome and inefficient to offer each of these separately, and physicians would not participate – indeed, this is reflected by the fact that these separate services and products are not being offered by providers. Absent market power, it should not be illegal for the entire program to determine a price for the combined package and negotiate it collectively with health plans.

The Agencies have acknowledged that at least some or all of the above rationales apply to the type of CI program described in the accompanying AHA *Guidance*, and that, therefore, the joint price negotiations should be viewed as passing the "ancillarity test." This is reflected in the discussion in the *Health Care Policy Statements* regarding clinical integration[65] and the FTC's Advisory Opinion in *MedSouth, GRIPA* and *TriState*.[66] While it is expected that the Agencies and courts will need to consider each arrangement on its own merits, there should be a strong presumption that – when CI programs are structured in a way that is substantially consistent with the steps described in the AHA *Guidance* – joint negotiations are ancillary to the clinical integration. This is no different than the presumption that the Agencies make about the ancillarity of joint negotiations involving financially-integrated provider networks.[67]

Transactions cost literature. The rationale for joint contracting set out above is that joint contracting overcomes many of the problems and uncertainties associated with efforts to achieve quality and cost improvements through individual contracting. Economic analysis, particularly insights from the literature involving transactions costs, theory of the firm, and network economics, provides further support for the conclusion that joint negotiation and contracting by the CI program is likely to achieve better results than independent contracting. This literature examines organizations and attempts to understand how the "cost of doing business" might explain the choices of a particular contracting form and the success – or lack thereof – of others.

The most relevant discussion of these issues is contained in an FTC Working Paper authored by Seth Sacher and Louis Silvia.[68] This paper compared independent versus joint contracting between physicians and managed care plans. It addressed "residual rights" or ownership rights to the assets or gains from physician integration and the under-investment in technologies or efforts that can occur when payers (and not physicians) are the ones establishing the terms of the contracting and operations of the program.

The authors identify three circumstances in which joint contracting by physicians may yield significant gains over independent and individual contracting between physicians and payers. These include situations:

- **where it is difficult for individual contracts to cover all of the necessary elements of physician behavior and payoff for a sufficiently broad scope and sufficient duration of activity.** This is particularly relevant in the context of quality improvements that require significant and specific investments and changes by physicians, and which are not static, *i.e.*, may need continual modification over time and over several contract cycles to achieve the intended results;
- **where joint pricing may be necessary to achieve the resulting program or to obtain the appropriate compensation or compensation mechanisms to attract and maintain the needed set of physicians**. The paper observes that "[d]epriving the physician-controlled network of the ability to make such pricing decisions [about how much physicians would be paid] may well have negative incentive effects with respect to the network specific investments at both the physician and the network level."[69]; and
- **where physician (as opposed to payer) control may be the most efficient and effective means for accomplishing needed changes and intended results.** The authors note several reasons why physician control may be more efficient than payer control,[70] and conclude by commenting that the efficiency gains are likely to be greatest where relatively sophisticated medical cost control stratagems are attempted.

In short, the Sacher/Silvia analysis is entirely consistent with the discussion above. The article also helps explain why attempts by managed care plans to achieve significant clinical and cost improvements through independent contracts are difficult, and why CI programs hold such promise.

Additional issues. In considering ancillarity, the Agencies may examine whether the scope of the joint negotiations is overly broad because they encompass providers who are not involved in the CI program. Obviously joint negotiations cannot cover providers who do not participate in the program's efficiency-enhancing endeavors. On the other hand, the requisite level of participation may necessarily vary among different provider specialties.

Most CI programs, quite logically, will begin with initiatives that have the best potential return on investment because they apply to a large number of patients or are in areas that hold the promise for the most significant improvement. While many of these initiatives may apply to all participating providers, a number will be targeted either to PCPs or to some specific specialists, such as cardiologists, endocrinologists, or orthopedic surgeons. Thus, at the outset, some of the participating physicians will be "touched" less by the program than others. But that does not mean that they are not active participants, or that they should be carved out of the

jointly-negotiated contracts. To be effective, some CI programs will need to offer a broad panel of physicians – covering many specialties. Moreover, the involvement of many specialists at the outset can facilitate the expansion of the program to include more focused initiatives aimed at various specialists as the program evolves and gains experience.[71] In other situations, CI programs may wish to begin by focusing only on PCPs.

Where hospitals work closely with physicians in developing and implementing a CI program, for all the reasons noted above, it also will be reasonable for joint negotiations to cover both hospital and physician contracts.

C. Competitive effects under a rule of reason analysis

We address here two issues that may arise in assessing the competitive effects of a CI program: exclusivity and the analysis of the program's negotiated prices.

Exclusivity. It is not always clear, from an antitrust perspective, whether it is preferable that a CI program be non-exclusive (that is, its members are available to, and do in fact contract with, health plans outside of the program) or exclusive (that is, the physicians are only willing to contract with health plans through the program).

On one hand, an exclusive program often may hold a greater promise for efficiencies than does a non-exclusive program, as the providers will have committed themselves entirely to its success. An exclusive program is also the most reliable way of assuring program participants that their colleagues will not "free ride" off their efforts and compete directly with them.

On the other hand, programs that are truly non-exclusive generally are viewed as posing substantially fewer risks of anticompetitive effects than those that are exclusive because payers can bypass the program altogether if they wish. If health plans like the product offered by the program, they can purchase it; if they do not, they can always contract independently with the provider. As a result, the *Health Care Policy Statements* provide more latitude for non-exclusive programs; for example, financially-integrated physician networks that are non-exclusive receive "safety zone" treatment if they include no more than thirty percent of the physicians in each physician specialty in the relevant geographic market, but must include no more than twenty percent of the physicians if the program is exclusive.[72] Similarly, the *MedSouth* advisory opinion relied heavily on assurances that the physician program would be non-exclusive,[73] as have numerous consents,[74] and FTC Advisory Opinions and DOJ Business Review Letters.[75]

Accordingly, CI programs should have the option of being either non-exclusive, or exclusive, depending on their particular circumstances, market requirements, and state of evolution in their own development. It is likely that in their early stages, many programs may seek to be non-exclusive while they develop their initiatives and have relatively few contracts. Thus, out of necessity, providers likely will need to contract outside the program. In addition, the program may start out with a relatively large number of providers with the expectation that a number of them who are unwilling or unable to meet the program's requirements will drop out. As the program matures, however, it could require a substantial exclusivity commitment as one aspect of its increased clinical integration. Other programs may take a different path and start out by requiring a very heavy investment in time and infrastructure, and from the very beginning view themselves as close to a "loose group practice", and therefore require exclusivity – just as law firms do.

Where CI programs operate on a completely non-exclusive basis, so that health plans are free to contract directly with providers, there is far less risk of anticompetitive effects. In effect, the program is offering health plans an alternative product which they are free to contract for, if they find it beneficial, or bypass and contract directly with the providers, if they are not interested.[76]

Effect on prices. The ultimate issue in the typical antitrust analysis is the effect of the conduct in question on prices. It is important, however, that in the case of CI, to compare the program's prices to those available in a competitive market *for the same services*.

To do this, it is essential to consider whether the services offered by the CI program are the same as those offered by the benchmark peer group to which it is compared. CI programs, however, are not necessarily offering the same "product" that providers can and do offer individually. Instead, the CI program is designed to enable providers to lower costs (which may involve reduced utilization), as well as to furnish higher quality services, or to offer a package of clinical services and the integration mechanism for achieving efficiencies. CI programs also may provide payers valuable transaction efficiencies, including the ability to access a broad panel with a single signature contract, credentialing, and assistance in provider relations tasks.

Thus, the appropriate analysis will not involve simply comparing the price-per-service that would be reflected in a negotiated fee schedule. Indeed, it may be the case that the price-per-service may increase through a CI program in order to compensate providers for their time and expense in developing and implementing the CI program and the higher value of the network product.[77] Thus, a better comparison would be based on the "quality-adjusted" price of furnishing the total array of health care services needed to provide a certain level of health care to a defined set of health plan enrollees. Such an approach would take into account savings to the health plan due to the reduction in unnecessary procedures, hospital admissions and other services, as well as the enhanced quality of services furnished through the network, and any savings due to transactional efficiencies. For reasons discussed above in connection with the difficulties of finding suitable benchmarks, however, it is likely to be very difficult to perform such a comparison in a rigorous manner.

CONCLUSION

We intend to continue our dialogue with the antitrust authorities and invite their comments in order to obtain some further assurances and to encourage the emergence of properly constructed clinical integration programs. This is not to say that the issues associated with clinical integration are simple. But given that this is an area that holds the promise of higher quality and efficient delivery of healthcare services, it is crucial that clinical integration initiatives should not be prematurely chilled by uncertainty about the appropriate antitrust standards.

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[2] Buntin MB, Jain SH, and Blumenthal D, "Health Information Technology: Laying The Infrastructure For National Health Reform," *Health Affairs,* 2010;29(6)1214-16

[3] Berwick DM, "Surer Footing for Medicare," *Washington Post* at A19 (September 3, 2010).

[4] Financial arrangements between hospitals and physicians must also be evaluated for compliance with other laws, including especially the federal "Stark" and anti-kickback laws, and federal and state laws relating to hospitals' tax exempt status.

[5] Am. Hosp. Ass'n, Aligning Hospital and Physician Interests: Broadening the Concept of Gain Sharing to Allow Care Improvement Incentives, Attachment A/2 (Fall 2005), *available at* http://www.aha.org/aha/about/Organization/board-actions.html (under Modernizing Gainsharing Opportunities).

[6] Am. Hosp. Ass'n, Trendwatch: Clinical Integration – The Key to Real Reform (February 2010), *available at http://www.aha.org/aha_app/trendwatch/archive.jsp* (hereinafter "AHA Trendwatch")

[7] Cortes D & Smoldt R, "Taking Steps Toward Integration," *Health Affairs,* 2007;26(1):w68-w71, at w68 (webexclusive publ'd Dec. 5, 2006).

[8] *Id.*

[9] Institute of Medicine ("IOM"), To Err is Human: Building a Safer Health System (Nat'l Academies Press, 2000).

[10] IOM, Crossing the Quality Chasm: A New Health System for the 21st Century (Nat'l Academies Press, 2001) (hereinafter IOM, Crossing the Quality Chasm).

[11] *Id.* at 20.

[12] IOM, Rewarding Provider Performance, Aligning Incentives in Medicare 20 (Nat'l Academies Press, 2007) (hereinafter IOM, Rewarding Provider Performance); *see also, e.g.*, Prometheus Payment, Inc., *Provider Payment for High Quality Care,* A White Paper (May 2006) (hereinafter Prometheus, *Provider Payment*); Am. Coll. of Physicians ("ACP"), *Linking Physician Payment to Quality*, A Position Paper (2005) (hereinafter ACP, *Linking Physician Payments*); Alice G. Gosfield, Contracting for Provider Quality: Then, Now and P4P, *Health Law Handbook* (A. Gosfield, ed. 2004); Leatherman S et al., "The Business Case For Quality: Case Studies And An Analysis," *Health Affairs* 2003;22(2):17-30.

[13] The HQA effort is intended to make it easier for the consumer to make informed health care decisions, and to support efforts to improve quality in U.S. hospitals. The major vehicle for achieving this goal is the Hospital Compare website: http://www.cms.hhs.gov/HospitalQualityInits/01_Overview.asp. Under the auspices of this initiative, hospitals collect and report their performance on a growing number of quality measures that have been extensively tested for validity and reliability. It is those results that are displayed on the Hospital Compare website.

[14] Fisher ES et al., "Creating Accountable Care Organizations: The Extended Hospital Staff Model," *Health Affairs,* 2007;26(1):w44-w57, at w53 (webexclusive publ'd Dec. 5, 2006) (hereinafter Fisher, Creating Accountable Care Organizations). Almost half of all private practice physicians are in practices with one or two physicians, and 82% are in practices of nine or fewer. Casalino LP et al., "Benefits of and Barriers to Large Medical Group Practice in the United States," *Archives of Internal Med.* 2003;163(16):1958-64, at 1960 (Table 2) (hereinafter Casalino, Benefits of and Barriers to Large Medical Group Practice).

[15] *See* Casalino LP, "The Federal Trade Commission, Clinical Integration, and the Organization of Physician Practice," *J. Health Politics, Policy & L.* 2006;31(3):569-85, at 581-82 (hereinafter Casalino, The Federal Trade Commission).

[16] *See* IOM, Crossing the Quality Chasm, *supra* note 10, at 39-40 (proposing six aims for improving health care, including that health care should be: (1) safe, (2) effective, (3) patient-centered, (4) timely, (5) efficient, and (6) equitable.

[17] For pay for performance, *see* Damberg CL et al., "Paying for Performance: Implementing a Statewide Project in California," *Quality in Managed Health Care* 2005;14(2):66-79; Dudley RA, "Pay-for-Performance Research: How to Learn What Clinicians and Policy Makers Need to Know," *JAMA* 2005;294(14):1821-23; Rosenthal MB et al., "Early Experience with Pay-for-Performance: From Concept to Practice," *JAMA* 2005;294(14):1788-93, at 1788 (hereinafter Rosenthal, Early Experience with Pay-for-Performance). For public reporting, *see* Rabinowitz DL & Dudley RA, "Public Reporting of Provider Performance: Can Its Impact Be Made Greater?," *Annual Rev. of Pub. Health* 2005;27(1):517-536.

[18] *See, e.g.*, AHA Trendwatch, *supra* note 6; Luft HS, "Universal Health Care Coverage: A Potential Hybrid Solution," 2007;297(10):1115-18, at 1116 (describing creation of "care delivery teams" composed of clinicians and facilities that can contract to provide services on an "episode of care" basis); Prometheus, *Provider Payment*, *supra* note 12, at 8-9 (suggesting the creation of "virtually" integrated groups of

providers that receive payment based on the provision of "care for discrete, clearly delineated clinical conditions in a coordinated manner"); Fisher, Creating Accountable Care Organizations, *supra* note 14, at w51-w53 (describing need to identify provider organizations that can be the locus of accountability for quality and costs).

[19] *See* Fisher, Creating Accountable Care Organizations, *supra* note 14, at w46.

[20] *Id.* at w45.

[21] *See* 42 CFR Parts 411 and 1001.

[22] Letters from Senators Kohl, Leahy, Feinstein, Whitehouse and Spector (November 3, 2009); from Senators M. Udall, Warner, Bennet, T. Udall, Burris, Gillibrand, Kirk, Hagan and Franken (December 23, 2009); and from Senators Cornyn, Graham, Coburn, Hatch, Roberts and Snowe (June 8, 2010).

[23] Dep't of Justice & Fed. Trade Comm'n, Improving Health Care: A Dose of Competition Ch. 2, pp. 39-40 (July 2004), *available at* http://www.ftc.gov/opa/2004/07/healthcarerpt.htm (hereinafter DOJ/FTC, Improving Health Care).

[24] *Id.* at 40.

[25] The focus here is on hospital-based clinical integration programs that involve hospitals working closely with their physicians on their medical staffs; much of the *Guidance*, however, would also be applicable to efforts by any group of providers to organize themselves in a clinically-integrated fashion.

[26] Dep't of Justice & Fed. Trade Comm'n, *Statements of Antitrust Enforcement Policy in Health Care* (Aug. 1996), *available at* http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm (hereinafter DOJ/FTC, *Statements of Antitrust Enforcement Policy in Health Care*).

[27] *See, e.g.*, Casalino LP et al., "External Incentives, Information Technology, and Organized Processes to Improve Health Care Quality for Patients with Chronic Diseases," *JAMA* 2003;289(4):434-41, at 435 (describing "care management processes" as various organizational processes that physicians can use to improve quality, and can include such approaches as cases management, performance feedback, disease registries and clinical practice guidelines); Bodenheimer T et al., "Improving Primary Care for Patients with Chronic Illness," *JAMA* 2002;288(14)1775-79, at 1775-76 (describing the elements of the "Chronic Care Model").

[28] DOJ/FTC, *Statements of Antitrust Enforcement Policy in Health Care*, *supra* note 26, at Statement 8, p. 51.

[29] Thus, for example, the Agencies have established in their *Health Care Policy Statements* a "safety zone" for financially-integrated exclusive networks that include 20% or fewer of the physicians in each physician specialty with active hospital staff privileges in the relevant geographic market. *Id.* at 50.

[30] Landon BE et al., "Physician Clinical Performance Assessment: Prospects and Barriers," *JAMA* 2003;290(9):1183-89 (hereinafter Landon, Physician Clinical Performance Assessment) (describing the characteristics of ideal performance measures for physicians and comparing the advantages and disadvantages of using process or outcome measures).

[31] IOM, Performance Measurement: Accelerating Improvement, Ch. 4 (Nat'l Academies Press, 2006) (hereinafter IOM, Performance Measurement) (focusing on how the quality of health care services should be measured); Medicare Payment Advisory Comm'n, Report to Congress: Medicare Payment Policy, Ch. 4, pp. 196-202 (Mar. 2005) (discussing structural, process, and outcomes measures in quality assessment); ACP, *Linking Physician Payments*, *supra* note 12, at 20-24 (discussing selection of performance measures); Alice Gosfield, "The Performance Measures Ball: Too Many Tunes, Too Many Dancers?," *Health Law Handbook*, Ch. 4 (A. Gosfield, ed. 2005) (exploring various types of performance measures); Brook RH et al., "Part 2: Measuring Quality of Care," *N. Engl. J. Med.* 1996;335(13):966-70 (reviewing various approaches to the assessment of quality and describing some of their advantages and disadvantages).

[32] *See, e.g.*, Jamtvedt G et al., "Audit and Feedback: Effects on Professional Practice and Health Care Outcomes," *Cochrane Database of Systematic Reviews*, 2003;3:CD000259 (a systematic review of 85 randomized trials showing that audit and feedback have small to moderate effects on physician practice); Thomas RE et al., "Effect of Enhanced Feedback and Brief Education Reminder Messages on Laboratory Test Requesting in Primary Care: A Cluster Randomised Trial," *Lancet* 2006:367:1990-96 (showing that feedback reduced ordering of unnecessary laboratory tests by physicians).

[33] For example, rewarding physicians who improve most compared to their own historical levels will penalize those who have performed well all along. On the other hand, rewarding physicians who perform well compared to other providers may raise more questions as to the validity of the comparisons (for

example, it may be harder to control for possible differences in patient acuity), and may be less effective in improving average overall performance. *See* Rosenthal, Early Experience With Pay-for-Performance, *supra* note 17, at 1788 ("Paying physicians to reach a common, fixed performance target may produce little gain in quality for the money spent and will largely reward those with higher performance at baseline.").

[34] *See* Letter from Jeffrey W. Brennan, Ass't Dir., Health Care Servs. & Prods., Bur. of Comp., FTC, to John J. Miles, Esq. (Feb. 19, 2002), 2002 WL 4633290, at *1, *11, *available at* http://www.ftc.gov/bc/adops/medsouth.htm (hereinafter MedSouth Advisory Op.).

[35] *See Nat'l Soc'y of Prof'l Engineers v. U.S.*, 435 U.S. 679, 689 (1978) ("The Rule of Reason . . . has been regarded as a standard for testing the enforceability of covenants in restraint of trade which are ancillary to a legitimate transaction"); Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for Collaborations Among Competitors* §§ 1.2, 3.31, 3.36(b), *available at* http://www.ftc.gov/bc/guidelin.htm (hereinafter *Competitor Collaboration Guidelines*).

[36] *See State Oil Co. v. Kahn*, 522 U.S. 3, 10 (1997) ("Some types of restraints . . . have such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit, that they are deemed unlawful *per se*."); *Broadcast Music, Inc. v. Columbia Broadcast. Sys., Inc.*, 441 U.S. 1, 19-20 (1979); *Nat'l Soc'y of Prof'l Engineers v. U.S.*, 435 U.S. 679, 692 (1978) ("Agreements whose nature and necessary effect are so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality" are "illegal *per se*"); *Northern Pac. Ry. v. U.S.*, 356 U.S. 1, 5 (1958) ("There are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal . . . .").

[37] DOJ/FTC, *Statements of Antitrust Enforcement Policy in Health Care*, *supra* note 26.

[38] DOJ/FTC, Improving Health Care, *supra* note 23, at Ch. 2, p. 40.

[39] *See Competitor Collaboration Guidelines*, *supra* note 35, at § 3.36 ("Indeed, the primary benefit of competitor collaborations to the economy is their *potential* to generate such efficiencies.") (emphasis added); Deborah Platt Majoras, *The FTC: Fostering a Competitive Health Care Environment that Benefits Patients*, at 4, Remarks before the World Congress Leadership Summit, New York, N.Y. (Feb. 25, 2005), *available at* www.ftc.gov/speeches/majoras.htm ("[T]he FTC (together with DOJ) committed long ago to using a balancing test (in our legal parlance, the 'rule of reason') to evaluate those physician network joint ventures that involve significant *potential* for creating efficiencies through integration.") (emphasis added); MedSouth Advisory Op., *supra* note 34, at *6 (concluding that MedSouth's "overall proposed course of conduct" should not be accorded *per se* treatment because MedSouth involved: (1) partial physician integration, (2) which had the *potential* to increase quality and reduce costs of medical care, and (3) joint contracting that appeared sufficiently related to, and reasonably necessary for, the achievement of *potential* benefits) (emphasis added).

[40] *See* McGlynn EA et al., "The Quality of Health Care Delivered to Adults in the United States," *N. Engl. J. Med.* 2003;348(26):2635-45 (national study showing that, across a wide range of medical services, patients receive appropriate care on average only slightly more than half the time); Casalino, Benefits of and Barriers to Large Medical Group Practices, *supra* note 14, at 1960-61, 1962 (finding that the problems identified nearly seventy years ago by the Committee on the Costs of Medical Care still exist today); IOM, Crossing the Quality Chasm, *supra* note 10, at 2 (expressing the concern of consumers, providers, and health leaders that in spite of persistent attention to improving our health system, there remain drastic problems in quality of care); Cabana M et al., "Why Don't Physicians Follow Clinical Practice Guidelines? A Framework for Improvement," *JAMA* 1999;282:1458-65, at 1458 (finding that, in spite of widespread dissemination of clinical practice guidelines, there has been little overall effect on physician behavior); Bodenheimer T, "The American Health Care System – The Movement for Improved Quality in Health Care," *New Eng. J. Med.* 1999;340(6):488-92, at 488 (categorizing the three main problems with the provision of quality health services and detailing the efforts of both private and public organizations to solve issues of quality and efficiency in health care); Chassin MR & Galvin RW, "The Urgent Need to Improve Health Care Quality," *JAMA* 1998;280:1000-05, at 1000 ("Current efforts to improve will not succeed unless we undertake a major systematic effort to overhaul how we deliver health care services, educate and train clinicians, and assess and improve quality.").

[41] *Statements of Antitrust Enforcement Policy in Healthcare*, *supra* note 26, at Statement 8, p. 58 (emphasis added).

[42] *Id.* at Statement 8, p. 57.

[43] *Id.*

[44] Letter from Marcus H. Meier, Ass't Dir, Health Care Servs & Prods, Bur. of Comp., FTC to Christi J. Braun, Esq. (April 13, 2009), *available at* http://www.ftc.gov/opa/2009/04/tristate.shtm (hereinafter "Tristate Advisory Op."), at 16-17 (Although CI program was not initially being selective by excluding significant number of providers, the program's stringent requirements would likely ensure that those who do participate will be fully committed to the organization and its proposed program).

[45] Casalino, The Federal Trade Commission, *supra* note 15, at 572.

[46] *See, e.g.*, Bodenheimer T, "Helping Patients Improve Their Health-Related Behaviors: What System Changes Do We Need?" *Disease Mgmt.* 2005;8(5):319-30.

[47] *See, e.g.*, Tristate Advisory Op., *supra* note 44, at 20 (success in pilot program on diabetes treatment suggests that clinical integration arrangement had capability to measure and evaluate members' performance in other areas, even though such areas had not yet been well-defined).

[48] *See* Landon, Physician Clinical Performance Assessment, *supra* note 30 (describing various characteristics of ideal performance measures and discussing practical obstacles to their use).

[49] *See* IOM, Performance Measurement, *supra* note 31 (discussing the pros and cons of different measures and recommending a "starter set" of measures).

[50] *See, e.g.*, Kerr EA et al., "Building a better quality measure: are some patients with 'poor quality' actually getting good care?" *Med. Care* 2003;41(10):1173-82 (showing that simple intermediate outcome measures of the type that are commonly available can be an inaccurate reflection of true quality, and that many patients classified as having substandard care by these measures are actually receiving high quality care); Rosenberg AL et al., "Accepting Critically Ill Transfer Patients: Adverse Effect on a Referral Center's Outcome and Benchmark Measures," *Ann. Intern. Med.* 2003;138(11):882-90 (showing that quality measurements are badly skewed unless adjusted for the health of the patient population, a difficult task to carry out); Fetterolf D et al., "Estimating the Return on Investment in Disease Management Programs Using a Pre-Post Analysis," *Disease Mgmt.* 2004;7(1):5-23 (describing the many pitfalls of using pre-post analysis to measure the performance of health care organizations).

[51] Leary TB, "The Antitrust Implications of 'Clinical Integration:' An Analysis of FTC Staff's Advisory Opinion in MedSouth," *St. Louis U. L.J.* 2003;47:223-34, at 232 ("Suppose you were to assume that the 'service' the doctors are selling is not the provision of tests and procedures, but rather better health?").

[52] Letter from David R. Pender, Act. Ass't Dir., Health Care Servs. & Prods, Bur. of Comp., FTC, to Clifton E. Johnson, Esq. (Mar. 28, 2006), *available at* http://www.ftc.gov/bc/healthcare/industryguide/advisory.htm#2006 (hereinafter Suburban Health Organization, Inc. ("SHO") Advisory Op.).

[53] *See Competitor Collaboration Guidelines*, *supra* note 35, at §§ 1.2, 3.3.

[54] *See id.* at § 4.2.

[55] *Cf.* Letter from Marcus H. Meier, Ass't Dir, Health Care Servs & Prods, Bur. of Comp., FTC to Christi J. Braun, Esq. (Sept. 17, 2007), *available at* http://www.ftc.gov/opa/2007/09/clinicalintegration.shtm (hereinafter "GRIPA" Advisory Op.), at 19 (GRIPA's non-exclusive nature and apparent absence of market power reinforces the view that its program is substantial and any competitive restraints are ancillary to it, because it would make no sense to make such investments where there was little likelihood that any collective negotiations would succeed in obtaining higher prices).

[56] *See supra* note 35 and surrounding text.

[57] *Competitor Collaboration Guidelines*, *supra* note 35, at § 3.36(b); *see also Nw. Wholesale Stationers, Inc. v. Pac. Stationary & Print. Co.*, 472 U.S. 284, 297 n.7 (1985) (The restraint should be "substantially related to the efficiency-enhancing or procompetitive purposes"); *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 224 (D.C. Cir. 1986) ("The restraint imposed must be related to the efficiency sought to be achieved.").

[58] *Polk Bros., Inc. v. Forest City Enter.*, 776 F.2d 185, 189 (7th Cir. 1985); *see also SCFC ILC, Inc. v. Visa USA, Inc.*, 36 F.3d 958, 970 (10th Cir. 1994) (Restraints that are "reasonably related" to the venture's operations and makes them "more effective in accomplishing its purposes" should be assessed under the rule of reason).

[59] *See Competitor Collaboration Guidelines*, *supra* note 35, at § 3.36(b).

[60] *Id.*

[61] *See id.*

[62] *See* MedSouth Advisory Op., *supra* note 34, at *8 ("In order to establish and maintain the on-going collaboration and interdependence among physicians from which the projected efficiencies flow, the doctors need to be able to rely on the participation of other members of the group in the network and its activities on a continuing basis . . . In the absence of the group being able to assure continuing participation of its members in its contracts, some of the benefits are likely to go unrealized."); GRIPA Advisory Op., *supra* note 55, at 18-19 ("Joint contracting on agreed-upon terms by its physician members will facilitate GRIPA's establishment of a pre-determined network of physicians, which is necessary for maximally effective operation of the various potentially-efficiency-enhancing activities that make up its proposed program.").

[63] *See id.* ("Joint contracting may permit the network to allocate the returns among members of the network in a way that creates incentives for the physicians to make appropriate investments of time and effort in setting up and implementing the proposed program.").

[64] TriState Advisory Op., *supra* note 44, at 27.

[65] *See* DOJ/FTC *Statements of Antitrust Enforcement Policy in Health Care, supra* note 26, at Statement 8, pp. 67-68 (discussing example of "Charlestown IPA," a clinically-integrated physician network and concluding that "[t]he price agreement, under these circumstances, is subordinate to and reasonably necessary to achieve [the network's] objectives").

[66] *See* MedSouth Advisory Op., *supra* note 34, at *8; GRIPA Advisory Op., *supra* note 55, at 18-20; TriState Advisory Op., *supra* note 44, at 26-28.

[67] Thus, for example, the *Health Care Policy Statements* provide a safety zone for financially-integrated networks below a certain market share without mentioning the need to consider the ancillarity of agreements on price. DOJ/FTC *Statements of Antitrust Enforcement Policy in Health Care, supra* note 26, at Statement 8, pp. 50-55. Such agreements are not inherent in all financially-integrated arrangements – for example, arrangements involving substantial financial withholds. But the Agencies conclusively presume that there is ancillarity given their familiarity with the arrangements and their understanding that joint negotiations are generally reasonably related to arrangements of this type.

[68] Seth Sacher & Louis Silvia, Physician Networks, Integration and Efficiency, Apr. 1998, FTC Working Paper, *available at* http://www.ftc.gov/be/workpapers/wp218.pdf.

[69] *Id.* at 24.

[70] The authors suggest three reasons why reputational and promotional efforts may be more easily secured with physician control: (1) the gains of opportunistic behavior at the network level (and losses at the physician level) would be internalized; (2) opportunism by payers may be reduced due to economies of scale in monitoring and enforcing contracts; and (3) there may be savings in governing physician network contracts since physicians may be in the best position to solve problems or obtain the cooperation of their peers. *Id.* at 16-17. All of these likely apply with most physician networks.

[71] The FTC Advisory Opinion in *Suburban Health* questioned the potential efficiencies of a particular program on the ground that it did not cover specialists, and therefore there was no assurance that specialists would adhere to the program's guidelines or other efficiency-enhancing initiatives. SHO Advisory Op., *supra* note 52, at 5-6. This caveat should be given a sensible interpretation. Obviously, it would put most CI programs in an untenable box if they failed antitrust scrutiny because they could neither include specialists in the program who necessarily had relatively fewer initiatives apply to them, nor exclude them because it called into question the entire potential of the program.

[72] *See* DOJ/FTC *Statements of Antitrust Enforcement Policy in Health Care, supra* note 26, at Statement 8 § A.

[73] *See* MedSouth Advisory Op., *supra* note 34, at *10.

[74] *In the Matter of Advocate Health Partners, et al.*, Docket No. C-4184 (2006); *In the Matter of California Pac. Med. Group, Inc.*, d/b/a Brown and Toland Medical Group, Docket No. 9306 (2004).

[75] *See, e.g.*, Letter from Charles A. James to Clifton E. Johnson 2 (Apr. 3, 2002), *available at* http://www.usdoj.gov/atr/public/busreview/10933.htm; Letter from Charles A. James to Patrick R. Gordon 2-3 (Aug. 29, 2001), *available at* http://www.usdoj.gov/atr/public/busreview/8973.htm; Letter from Joel Klein to Christopher H. Casey 5 (Sept. 15, 1998), *available at* http://www.usdoj.gov/atr/public/busreview/1941.htm; Letter from Robert F. Leibenluft to David V. Meany, Esq. 7 (May 14, 1997), *available at* http://www.ftc.gov/bc/adops/yelltone.htm.

[76] For cases addressing this issue, *see, e.g.*, ABA Section of Antitrust Law, Antitrust Law Developments 56, n.298 (5th ed. 2002).

[77] The FTC has recognized that prices in a lawful CI program may increase, but that such prices may actually be lower after adjusting for quality, and moreover, even if they are higher customers may be willing to pay the higher unit rates if it results in higher quality and reduces total expenditures. GRIPA Advisory Op., *supra* note 55, at 27.

American Hospital Association

Accountable Care ORGANIZATIONS

AHA RESEARCH SYNTHESIS REPORT

JUNE 2010

American Hospital Association
Committee on Research

AHA Research Synthesis Reports are periodic reports that synthesize literature on key issues related to the 2010 to 2012 AHA Research Agenda as part of Hospitals in Pursuit of Excellence. The AHA Committee on Research developed the 2010 to 2012 AHA Research Agenda, which was approved by the AHA Board in November 2009.

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hospitals in pursuit of excellence
Accelerating Performance Improvement

Accountable Care Organizations – AHA Research Synthesis Report
Executive Summary

Introduction

This AHA Research Synthesis Report presents an overview of Accountable Care Organizations (ACOs), including a discussion on the potential impact of ACOs, key questions to consider in developing an ACO, and a review of the key competencies needed to be an effective ACO. This report focuses on the overall concept of ACO yet highlights the specifics of the ACO model proposed in health reform legislation.

What are ACOs?

The term Accountable Care Organization (ACO) describes the development of partnerships between hospitals and physicians to coordinate and deliver efficient care (Fisher, 2006). The ACO concept envisions multiple providers assuming joint accountability for improving health care quality and slowing the growth of health care costs. The concept was also included in national health care reform legislation as one of several demonstration programs to be administered by Medicare (Patient Protection and Affordable Care Act, 2010). However, ACOs described in health reform legislation are operationally different from other ACO models. The role of ACOs in integrating and aligning provider incentives in care delivery requires participating organizations to posses certain key competencies, as identified in the literature:

	Key Literature on ACOs					
Required Organizational Competencies for ACOs	Health Reform (2010)	Shortell/ Casalino (2010)	McClellan/ Fisher (2010)	Miller (2009)	Fisher/ McClellan (2009)	MedPAC (2009)
1. Leadership	x	x	N/A	x	N/A	N/A
2. Organizational culture of teamwork	N/A	x	N/A	x	N/A	x
3. Relationships with other providers	x	x	x	x	x	x
4. IT infrastructure for population management and care coordination	x	x	x	x	x	x
5. Infrastructure for monitoring, managing, and reporting quality	x	x	x	x	x	x
6. Ability to manage financial risk	N/A	x	x	x	x	x
7. Ability to receive and distribute payments or savings	x	x	x	x	x	x
8. Resources for patient education and support	x	x	N/A	x	N/A	N/A

Information on the impact of ACOs is limited and points to key questions that still need to be answered as both the federal and private sectors prepare for widespread implementation of the model.

Key Questions to Consider

The following are key questions to consider in the development and implementation of ACOs.

1. What are the key competencies required of ACOs?
2. How will ACOs address physician barriers to integration?
3. What are the legal and regulatory barriers to effective ACO implementation?
4. How can ACOs maintain patient satisfaction and engagement?
5. How will quality benchmarks be established?
6. How will savings be shared among ACOs?

Introduction

Under the charge of the AHA Committee on Research, the AHA Research Synthesis Reports seek to answer parts of the AHA's top research questions. This AHA Research Synthesis Report addresses the following question from the AHA Research Agenda:

What is the role of the hospital in a new community environment that provides more efficient and effective health care (e.g., what are the redesigned structures and models, the role and implementation of accountable care organizations, the structures and processes needed to implement new payment models such as bundled payments, and how do organizations transition to this new role)?

This report is the second in the series and presents an overview of Accountable Care Organizations (ACOs), including a discussion regarding the potential impact of ACOs, key questions to consider in developing an ACO, and a specific review of the key competencies needed to be an effective ACO.

What are Accountable Care Organizations?

The term Accountable Care Organization (ACO) was formalized by Dr. Elliott Fisher in a 2006 *Health Affairs* article to describe the development of partnerships between hospitals and physicians to coordinate and deliver efficient care (Fisher, 2006). The ACO concept, which had been in existence before the Elliot Fisher article, seeks to remove existing barriers to improving the value of care, including a payment system that rewards the volume and intensity of provided services instead of quality and cost performance and widely held assumptions that more medical care is equivalent to higher quality care (Fisher et al., 2009).

The ACO concept envisions the development of legal agreements between hospitals, primary care providers, specialists, and other providers to align the incentives of these providers to improve health care quality and slow the growth of health care costs. ACOs would reach these goals by promoting more efficient use of treatments, care settings, and providers (Miller, 2009).

The success of the ACO model in fostering clinical excellence and continual improvement while effectively managing costs hinges on its ability to incentivize hospitals, physicians, post-acute care facilities, and other providers involved to form linkages that facilitate coordination of care delivery throughout different settings and collection and analysis of data on costs and outcomes (Nelson, 2009). This predicates that the ACO will need to have organizational capacity to establish an administrative body to manage patient care, ensure high quality care, receive and distribute payments to the entity, and manage financial risks incurred by the entity.

The ACO model was included in national health care reform legislation as one of several demonstration programs to be administered by the Centers for Medicare and Medicaid Services (CMS), along with bundled payment and other key care delivery approaches. ACOs participating in the CMS program would assume accountability for improving the quality and cost of care for a defined patient population of Medicare beneficiaries. As proposed, ACOs would receive part of any savings generated from care coordination as long as benchmarks for the quality of care are also maintained. Health care reform provides a definition for the ACO model included in the demonstration programs. However, many details have yet to be defined.

Many experts believe ACOs in general will include certain core characteristics, including the participation of a diverse group of providers—including primary care physicians, specialists, and a hospital—and the ability to administer payments, determine benchmarks, measure performance indicators, and distribute shared savings (Deloitte, 2010). However, they could vary in their structure and payment model. For example, the ACO program proposed in health reform legislation limits provider exposure to financial risks, as it does not deviate from the current fee-for-service payment system and includes no payment penalties. On the other hand, ACOs that are being paid a fixed price are responsible for financial gain or loss.

This report focuses on the overall concept of the ACO and will attempt to highlight specifics of the ACO model proposed in health reform legislation where differences appear in existing literature.

Distinguishing Between ACOs and Earlier Care Delivery Initiatives

Health maintenance organizations (HMOs) and patient-centered medical homes (PCMHs) share commonalities with the ACO concept as large-scale attempts to improve health care delivery and payment. Even though the ACO model builds upon these previous attempts at health care delivery reform, there are variations between the ACO model and HMOs and PCMHs.

ACOs and PCMHs

The PCMH model, which emphasizes strengthening and empowering primary care to coordinate care for patients across the continuum of care, can be viewed as being complementary to the ACO model (Devers and Berenson, 2009). Both models promote the utilization of enhanced resources—including electronic health records, patient registries, and increased patient education—to achieve the goal of improved care (Miller, 2009). However, unlike the ACO model, the PCMH does not offer explicit incentives for providers to work collaboratively to reduce costs and improve quality. Also, the PCMH model calls specifically for primary care providers to take responsibility for coordinating care, which could prove challenging if these providers do not have resources or established relationships with other providers to undertake these tasks.

The ACO model is expected to address some of the limitations in the PCMH model. For instance, the ACO model fosters accountability for care and costs by offering a joint payment to all providers involved in the provision of care. Also, the ACO model does not specify any type of provider to take the role as administrator of the ACO, but rather, offers characteristics for the types of organizations/providers that could assume the role of administrator. Also, unlike the PCMH model, a variety of payment models have been proposed for the ACO model, ranging from traditional fee-for-service payment to full capitation. Despite these key differences in the PCMH and ACO models, it is important to note that, far from being competing models, the PCMH structure could aid providers in taking on the additional accountability and administrative activities necessary to become an ACO.

ACOs and HMOs

The key difference between the ACO concept and HMOs lies in the payment structure and level of provider risk involved. While HMOs have typically been arranged around capitation, ACOs

recognize variation in regional health care markets and the ability of providers to accept new payment models (Devers and Berenson, 2009). One proposed payment approach for public and private-sector ACO programs is the "shared savings" approach, used in the Brookings-Dartmouth and Medicare ACO program, where providers receive regular fee-for-service payment but qualify to share in any savings resulting from cost reduction and meeting predetermined performance and/or utilization targets. Other payment methods proposed in current literature for ACOs include a bundled payment, negotiated by the providers and payers, for an episode of care or capitation, similar to HMOs. It is important to note that the type of payment approach adopted is closely related to the level of financial risk that the providers are expected to assume. The primary criticism of the HMO model is that by making cost reduction its primary goal it sometimes sacrificed the quality of care. Providers participating in HMOs have also complained about the inadequate payment rates and high level of financial risk involved in the HMO model. Policymakers believe the ACO model incorporates some of these lessons learned from the HMO model.

ACOs and Health Care Reform

The Patient Protection and Affordable Care Act calls for the creation of an ACO program administered by CMS by January 1, 2012. Qualifying providers, including hospitals, physician group practices, networks of individual practices, and partnerships between hospitals and other health care professionals will be eligible to form ACOs. ACOs will "be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it" and will also be expected to meet specific organizational and quality performance standards—which are still to be determined by CMS—in order to be eligible to receive payments for shared savings. The legislation does not provide specifics on how ACOs will be held financially accountable, as they will not be subject to financial risks in the form of payment penalties if they do not achieve their savings targets (CMS, 2010). Some of the additional stipulations for ACOs include:

- ACOs must have a formal legal structure to receive and distribute shared savings to participating providers.
- Each ACO must employ enough primary care professionals to treat their beneficiary population (minimum of 5,000 beneficiaries) as deemed sufficient by CMS.
- Each ACO must agree to at least three years of participation in the program.
- Each ACO will have to develop sufficient information about their participating health care professionals to support beneficiary assignment and for the determination of payments for shared savings.
- ACOs will be expected to include a leadership and management structure that includes clinical and administrative systems.
- Each ACO will be expected to have defined processes to promote evidence-based medicine, report on quality and cost measures, and coordinate care.
- ACOs will also be required to produce reports demonstrating the adoption of patient-centered care.

CMS expects to release additional information about the ACO program this fall in a Notice of Proposed Rulemaking (CMS, 2010).

Potential Impacts of ACOs

Given the recent emergence of ACOs, providers considering participation in the CMS program do not have a long history of research on practicing ACOs to review. A limited amount of research exists on payment and delivery initiatives similar to ACOs that have been tested since as early as 1998 (shown in Box 1). These models include a combination of federal, regional, state, and local initiatives. These efforts offer some evidence on the potential impact of ACOs to reduce costs, improve coordination, and better align incentives of providers, payers, and patients. These efforts also share some of the critical characteristics of the ACO concept, including care coordination, evidence-based practice, and the sharing of savings based on improvements in quality and reductions in cost.

Box 1 – Precursors of ACOs

Community Care of North Carolina

Since 1998, the state of North Carolina has operated Community Care of North Carolina, an enhanced medical home supported by the state's Medicaid program. The program builds community health networks organized collaboratively by hospitals, physicians, health departments, and social service organizations to manage care. Each enrollee is assigned to a specific primary care provider, while network case managers work with physicians and hospitals to identify and manage care for high-cost patients. A study by the University of North Carolina found that the program saved roughly $3.3 million in the treatment of asthma patients and $2.1 million in the treatment of diabetes patients between 2000 and 2002, while reducing hospitalizations for both patient groups. In 2006, the program saved the state roughly $150 to $170 million (Kaiser Commission, 2009).

Physician Group Practice Demonstration

In 2005, Medicare developed the Physician Group Practice Demonstration, a group of ten provider organizations and physician networks to test shared savings. Providers are incentivized to coordinate care delivered to Medicare patients. Physician groups receive cost and quality performance payments if they achieve Medicare savings of more than two percent and additional bonuses beyond the two percent threshold. Performance payments are designed to reward both cost efficiency and performance on 32 quality measures phased in through the life of the demonstration. Through year three of the program, all ten participating sites achieved success on most quality measures, and five collectively received over $25 million in bonuses as a share of $32 million in Medicare cost reductions (McClellan et al., 2010).

Pathways to Health, Battle Creek, Michigan

In 2006 Integrated Health Partners participated in a chronic disease initiative with Blue Cross Blue Shield of Michigan (BCBSM). The initiative was later restructured into Pathways to Health, a framework that includes several local health care stakeholders such as insurers, consumers, and employers interested in reducing hospitalization and improving chronic care delivery in their area. Pathways to Health features key ACO concepts such as a patient-centered medical home, value-based purchasing, and community buy-in. The collaborative is currently developing a new payment structure and improving its patient data collection efforts. BCBSM reports that hospitalizations for conditions that can be prevented via better ambulatory care have dropped 40 percent over the three-year life of the program (Simmons, 2009).

Even though the models in Box 1 include some characteristics of ACOs and could provide some insight in the impact of ACOs, federal and private sector ACO programs (Box 2) that are currently underway or planned for the future could provide better lessons for providers and payers interested in participating in ACOs.

Box 2 – Sample ACO Pilots

Brookings/Dartmouth Accountable Care Collaborative
The Brookings Institution and the Dartmouth Institute for Health Policy are currently collaborating on the development of an ACO model focusing on local accountability, shared savings, and enhanced performance measurement. Roanoke, Virginia-based Carilion Clinic, a multi-specialty group practice with more than 500 physicians and seven hospitals, has been selected by the Brookings/Dartmouth collaborative as a pilot site for ACO adoption, along with Norton Health System in Louisville and Tucson Medical Center in Arizona.

Baylor Health System
Dallas-based Baylor Health System, a 13-hospital system with 4,500 physicians, is currently developing an ACO model with a bundled payment system to control costs and improve care coordination. Baylor is directly marketing the ACO concept to employers, offering lower costs in exchange for participation in specific health insurance plans (Deloitte, 2010).

Robert Wood Johnson Foundation Medical School
A pilot ACO program at Robert Wood Johnson Foundation Medical School in New Jersey will engage 100-500 physicians, several specialties, and six hospitals (Deloitte, 2010). The ACO's payment structure is still to be determined, but system leaders envision that the effort will link up the Robert Wood Johnson Medical Group—the state's largest multi-specialty network—with the 30 to 40 percent of primary care practices that have existing relationships with the school (Nelson, 2009).

Premier ACO Collaboratives
In May 2010, the Premier health care alliance announced plans to launch a two-track system for its member hospitals to participate in an ACO. The first effort, the ACO Implementation Collaborative, will consist of members who already possess the critical characteristics and relationships needed for successful ACO participation. The second effort, the ACO Readiness Collaborative, is designed to prepare hospitals by helping them to develop the skills and operational capacity necessary to implement in the future. To date, 70 hospitals and 5,000 physicians in 15 states have signed up for the two collaboratives.

Key Questions to Consider

Hospitals and other providers interested in participating in private sector and CMS ACO programs need to consider their preparedness in the face of the limited information available and identify steps to undertake to facilitate participation in the emerging ACO programs. To aid hospitals, physician groups, and other organizations in making this assessment, we identify the following key questions in Box 3 that still need to be addressed and attempt to answer them with information available from the literature.

Box 3 – Key Questions on ACOs

1. What are the key competencies required of ACOs?
2. How will ACOs address physician barriers to integration?
3. What are the legal and regulatory barriers to effective ACO implementation?
4. How can ACOs maintain patient satisfaction and engagement?
5. How will quality benchmarks be established?
6. How will savings be shared among ACOs?

1. What are the key competencies required of ACOs?

In order to qualify for the CMS program, participating ACOs will have to formalize a management structure to coordinate operations between participating providers and create a system for distributing shared payment. In general, the tasks and goals of ACOs will require both the ACO administrator and participating providers to possess certain core competencies. The competencies outlined in Table 1 below are identified in recent key literature on ACOs.

Table 1: Required competencies for ACOs as determined by key ACO literature

Required Organizational Competencies for ACOs	Key Literature on ACOs					
	Health Reform (2010)	Shortell/ Casalino (2010)	McClellan/ Fisher (2010)	Miller (2009)	Fisher/ McClellan (2009)	MedPAC (2009)
1. Leadership	x	x	N/A	x	N/A	N/A
2. Organizational culture of teamwork	N/A	x	N/A	x	N/A	x
3. Relationships with other providers	x	x	x	x	x	x
4. IT infrastructure for population management and care coordination	x	x	x	x	x	x
5. Infrastructure for monitoring, managing, and reporting quality	x	x	x	x	x	x
6. Ability to manage financial risk	N/A	x	x	x	x	x
7. Ability to receive and distribute payments or savings	x	x	x	x	x	x
8. Resources for patient education and support	x	x	N/A	x	N/A	N/A

Legend:

- N/A – indicates that the authors do not explicitly discuss the competency in their literature.
- X – Even though the indicated authors discuss the key competencies, there may be differences in how they perceive the importance and application of the competencies in ACOs.

The structure of some care delivery organizations, such as Integrated Delivery Systems (IDSs) may facilitate the formation of an ACO because they may already possess the competencies identified in the literature. IDSs typically already assume some accountability for cost and quality, and often possess the population health data needed to effectively administer an ACO

(Miller, 2009). IDSs with high-functioning leadership structures to handle the legal and clinical requirements of the ACO model may be best prepared to qualify for an ACO at present (Hastings, 2009). Other care delivery organizations such as Multispecialty Group Practice (MSGP), Physician-Hospital Organization (PHO) and Independent Physician Association (IPA) may possess a partial list of the competencies and need to work on developing others. However, free-standing hospitals, post-acute care providers such as skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs), and small physician practices, can also position themselves to successfully participate in an ACO with appropriate technical assistance and/or practice redesign.

In addition to the core competencies identified in the literature above, there are other important competencies cited by thought leaders that could help organizations participating in an ACO acclimate to the novel care delivery and payment structure:

- ***Spread*** – ability to aggressively identify and disseminate best practices that promote efficiency of care delivery, improved quality of care, and reduced cost within an organization. This competency is important both at the individual institution level as well as the ACO level.
- ***Reach*** – established linkages between ACOs (or participating organizations) and public health/community resources in their catchment area to facilitate the transition of patients from the care delivery setting back into the community.
- ***Regional Health Information Exchange*** – participation in a multi-stakeholder health information exchange to share health care information with the goal of improving health and care in the community.

2. How will ACOs address physician barriers to integration?

Overcoming physician attitudes favoring autonomy and individual accountability over coordination will pose a major challenge to hospitals pursuing an ACO model, especially if they do not currently enjoy strong affiliations with physician groups who have admitting privileges (Fisher et al., 2006). Physician groups who are already part of integrated health systems may have an early edge in comparison to independent practice associations preparing to join an ACO. Physician groups will also have to be convinced that a strong business case exists for ACO development, and some groups may resist capitation and potential penalties for physicians related to quality performance, as have been proposed for some ACO models (Deloitte, 2010).

Other challenges may include deciding on the appropriate reimbursement model that is attractive to physicians and that falls within the existing legal requirements. Organizations participating in an ACO will also need to navigate differences in what they consider to be the appropriate use of potential shared savings. While hospitals may choose to use savings to offset any expenditures related to the ACO implementation or decrease in revenue stream resulting from reduction in volume, primary care physicians may choose to use the savings to pay for care management and information technology infrastructure (Miller, 2009).

3. What are the legal and regulatory barriers to effective ACO implementation?

The actualization of the ACO concept will prove challenging in the current legal environment. Sharing financial incentives across providers and incentivizing the use of evidence-based protocols can place participating providers at risk of violating federal laws that govern physician

self-referral for Medicare patients and laws that protect patients and federal health care programs from fraud and abuse.

Hospitals preparing to join both federal and private-sector ACO programs may need to assess and potentially revise their existing contracts with other providers also taking part in the ACO. Implementing the ACO concept, which may require hospitals and physicians and other providers to accept one payment for all services and share financial incentives, could be in violation of previous interpretations of the Anti-Kickback Statute and Civil Monetary Penalty Law (Fader, 2010). Uncertainty about the antitrust consequences will deter precompetitive, innovative arrangements. Nonprofit hospitals would need to determine whether their involvement with participating, for-profit physician practices as part of an ACO complies with IRS guidelines for nonprofit institutions (Fader, 2010).

The health care reform bill does not create safe harbors or exceptions that address the operation of ACOs under current laws. However, the bill does permit the Secretary of Health and Human Services (HHS) to waive the requirements of the Anti-kickback, Stark, and Civil Monetary Penalty laws as necessary to administer ACOs (Bass, Berry, and Sims, 2010).

4. How can ACOs maintain patient satisfaction and engagement?

Medicare beneficiaries participating in the ACO program may not necessarily be aware of their assignment within an ACO and will be able to continue to choose their providers, including those who are not participating in their assigned ACO (CMS, 2010). However, adequate patient education will still be necessary to ensure that patients do not regard the ACO model unfavorably. Patients will need to understand how ACOs will impact the care they receive in the form of better quality, efficient care, and improved health outcomes resulting from coordinated care.

Since health outcomes are largely dependent on patients' participation in care, providers will need to actively engage consumers in the care that they receive and ensure that patients have a basic understanding of health care costs and the importance of efficient care delivery (Miller, 2009). Lastly, ACOs could maintain accountability to patients by measuring and reporting on patients' experience of care, in addition to reporting on costs and health outcomes (Miller, 2009).

5. How will quality benchmarks be established?

A critical component of the administration of ACOs that has not been determined in federal health reform and other key literature pertains to the quality benchmarks to which providers will be held accountable. Health reform legislation leaves the final decision of measure selection for ACOs to federal health officials, and the available literature does not provide guidance on how to choose appropriate measures.

As the CMS program and other private ACO initiatives are established, it is important to ensure that the quality benchmarks established and how they are interpreted and reported are standardized nationwide. The measures will also have to be applicable to different care providers and span care settings to accommodate the set of providers included in an ACO.

Lastly, the benchmarks will need to include a combination of process, outcome, and patient experience measures in order to accurately evaluate all aspects of care provided.

6. How will savings be shared among ACOs?

Payment reform is an important component of ACOs, since it is the main vehicle for holding providers accountable for the quality and cost of care that they provide. Experts have proposed several payment approaches for ACOs, which correlate with the level of risk that providers are expected to assume. Shortell and Casalino propose a three-tiered approach for risk-reward payment. In the first tier, which involves no risk, providers will receive shared savings and bonuses for meeting defined quality measures and staying under the expected costs of delivering care to patients. In the second tier, providers will receive shared savings for managing costs and hitting quality benchmarks, and will be liable for care that exceeds spending targets. In the third tier, providers assume greater risk and are paid through full or partial capitation. They could also qualify for substantial bonuses for meeting quality and patient experience targets (Shortell and Casalino, 2010).

The proposed payment model in health reform is a combination of the first and second tier of the Shortell/Casalino model. However, the specifics of it are yet to be defined by federal health officials. The model of payment for any ACO, as well as associated bonuses and penalties, will have to be substantial enough to generate change in the way care is delivered.

Conclusions

While some parallels exist between ACOs and existing efforts to coordinate care and integrate provider activities, substantial gaps exist in how an ACO will be structured and the impact that it will actually have on care delivery, quality, and costs. The early consensus emerging from ACO researchers appears to be that the model shows some promise as a driver of both quality improvement and cost control via care coordination (Devers and Berenson, 2009).

Hospitals and health systems considering ACO participation should assess their capabilities in several key core competencies that will likely be necessary for successful ACO implementation, including IT infrastructure, resources for patient education, team-building capabilities, strong relationships with physicians and other providers, and the ability to monitor and report quality data. Providers should be prepared to make major investments in these areas where necessary (Shortell and Casalino, 2010). ACOs whose members already possess many of these characteristics are expected to be most successful at implementation in the short run (Deloitte, 2010). However, even providers who already possess key organizational, technical and clinical competencies may find that adjusting to an ACO will still require the sustained development and strengthening of those capacities in order to be successful (Devers and Berenson, 2010).

Appendix – Medicare ACO Q & A Document

Medicare "Accountable Care Organizations"
Shared Savings Program – New Section 1899 of Title XVIII

Preliminary Questions & Answers

CMS/Office of Legislation

The Affordable Care Act (ACA) improves the health care delivery system through incentives to enhance quality, improve beneficiary outcomes and increase value of care. One of these key delivery system reforms is the encouragement of Accountable Care Organizations (ACOs). ACOs facilitate coordination and cooperation among providers to improve the quality of care for Medicare beneficiaries and reduce unnecessary costs. This document provides an overview of ACOs and the Medicare Shared Savings Program.

Q: What is an "Accountable Care Organization"?

A: An Accountable Care Organization, also called an "ACO" for short, is an organization of health care providers that agrees to be accountable for the quality, cost, and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it.

For ACO purposes, "assigned" means those beneficiaries for whom the professionals in the ACO provide the bulk of primary care services. Assignment will be invisible to the beneficiary, and will not affect their guaranteed benefits or choice of doctor. A beneficiary may continue to seek services from the physicians and other providers of their choice, whether or not the physician or provider is a part of an ACO.

Q: What forms of organizations may become an ACO?

A: The statute specifies the following:

1) Physicians and other professionals in group practices
2) Physicians and other professionals in networks of practices
3) Partnerships or joint venture arrangements between hospitals and physicians/ professionals
4) Hospitals employing physicians/professionals
5) Other forms that the Secretary of Health and Human Services may determine appropriate.

Q: What are the types of requirements that such an organization will have to meet to participate?

A: The statute specifies the following:

1) Have a formal legal structure to receive and distribute shared savings
2) Have a sufficient number of primary care professionals for the number of assigned beneficiaries (to be 5,000 at a minimum)
3) Agree to participate in the program for not less than a 3-year period
4) Have sufficient information regarding participating ACO health care professionals as the Secretary determines necessary to support beneficiary assignment and for the determination of payments for shared savings.

5) Have a leadership and management structure that includes clinical and administrative systems
6) Have defined processes to (a) promote evidenced-based medicine, (b) report the necessary data to evaluate quality and cost measures (this could incorporate requirements of other programs, such as the Physician Quality Reporting Initiative (PQRI), Electronic Prescribing (eRx), and Electronic Health Records (EHR), and (c) coordinate care
7) Demonstrate it meets patient-centeredness criteria, as determined by the Secretary.

Additional details will be included in a Notice of Proposed Rulemaking that CMS expects to publish this fall.

Q: How would such an organization qualify for shared savings?

A: For each 12-month period, participating ACOs that meet specified quality performance standards will be eligible to receive a share (a percentage, and any limits to be determined by the Secretary) of any savings if the actual per capita expenditures of their assigned Medicare beneficiaries are a sufficient percentage below their specified benchmark amount. The benchmark for each ACO will be based on the most recent available three years of per-beneficiary expenditures for Parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO. The benchmark for each ACO will be adjusted for beneficiary characteristics and other factors determined appropriate by the Secretary, and updated by the projected absolute amount of growth in national per capita expenditures for Part A and B.

Q: What are the quality performance standards?

A: While the specifics will be determined by the HHS Secretary and will be promulgated with the program's regulations, they will include measures in such categories as clinical processes and outcomes of care, patient experience, and utilization (amounts and rates) of services.

Q: Will beneficiaries that receive services from a health care professional or provider that is a part of an ACO be required to receive all his/her services from the ACO?

A: No. Medicare beneficiaries will continue to be able to choose their health care professionals and other providers.

Q: Will participating ACOs be subject to payment penalties if their savings targets are not achieved?

A: No. An ACO will share in savings if program criteria are met but will not incur a payment penalty if savings targets are not achieved.

Q: When will this program begin?

A: We plan to establish the program by January 1, 2012. Agreements will begin for performance periods, to be at least three years, on or after that date.

Source: https://www.cms.gov/OfficeofLegislation/Downloads/AccountableCareOrganization.pdf

Key References

Proposals:

1. Fisher, E.S., Staiger, D.O., Bynum, J. and Gottlieb, D.J. (2006) Creating Accountable Care Organizations: The Extended Hospital Medical Staff. *Health Affairs* (26: w44-w57).

Summary: The article introduces the concept of accountable care organizations and explores the concept of the "extended hospital medical staff," defined as a hospital-associated multi-specialty group practice tightly aligned to a specific hospital through direct or indirect referrals. The article assesses a group of hospitals and their extended medical staffs on their performance with heart attacks, colon cancer, and hip fractures, finding that hospitals and extended medical staffs who performed high on quality measures tended to have tighter affiliations with each other. The authors conclude that the extended medical staff model can bolster performance measurement, foster local accountability for capacity decisions, and improve quality and lower costs. The article also outlines some of the barriers to change, including the fee-for service payment system, the cultural importance U.S. physicians traditionally place on autonomy and the difficulty less tightly aligned hospitals and physician groups will have in adjusting to a new model.
http://content.healthaffairs.org/cgi/content/abstract/26/1/w44

2. Fisher, E., McClellan, M., Bertko, J., Lieberman, S., Lee, J., Lewis, J. and Skinner, J. (2009) Fostering Accountable Health Care: Moving Forward in Medicare. *Health Affairs (Web exclusive).*

Summary: The authors survey the variation in health care costs and outcomes in the United States, and propose the ACO model as part of a major realignment of payment incentives to support providers in improving care. The article advocates for increased accountability for providers to improve quality and manage costs, a shift away from practices that reward providers based on the volume and intensity of services and the use of transparent, meaningful performance measures to evaluate results. The article calls for ACOs to create formal legal structures, assume responsibility for a defined population of Medicare beneficiaries, and participate in public reporting of performance measures. In exchange, ACOs would receive shared savings for meeting quality standards while keeping costs below defined benchmarks.
http://content.healthaffairs.org/cgi/reprint/28/2/w219

3. Shortell, S. and Casalino, L. (2010) Implementing Qualifications Criteria and Technical Assistance for Accountable Care Organizations. *Journal of the American Medical Association*, 303 (17): 1747-1748.

Summary: The authors suggest a three-tiered system of ACO qualification, with each level representing graduated levels of assumed risk and payment incentives. In this model, Level I ACOs would assume no financial risk but would be eligible for shared savings for meeting quality and spending targets. Level II ACOs would receive greater proportions of shared savings but would assume some risk for not meeting agreed-upon targets. Level III ACOs would be

paid through full or partial capitation. The article also explores the implementation hurdles that prospective ACOs must pass, including practice redesign, process improvement, EHR implementation and leadership development.

4. Miller, H. (2009) How to Create Accountable Care Organizations. *Center for Healthcare Quality and Payment Reform*.

Summary: This comprehensive assessment surveys the potential of the ACO model for improving quality and controlling costs, and examines the ways ACOs will impact primary care physicians, hospitals and consumers. The article notes several potential areas of improvement for hospitals participating in ACOs, including improved efficiency of patient care, the use of less costly treatment avenues, reductions in health care-acquired conditions and reductions in preventable admissions. The author concludes that ACOs will not adhere to a single formula, and asserts that while long-term improvements are possible, providers should prepare both organizationally and financially for an extended transition period.
http://www.chqpr.org/downloads/HowtoCreateAccountableCareOrganizations.pdf

5. MedPAC (2009) *Report to the Congress: Improving Incentives in the Medicare Program.* Chapter 2.

Summary: The report explores different potential models for ACOs administered by CMS, including a voluntary program with bonuses for meeting quality and spending targets and a mandatory model with physicians assigned to hospitals based on Medicare claims. The article concludes that ACOs could slowly incentivize change, emphasizing the importance ACOs will need to place on coordination, system thinking and constant refinement.
http://www.medpac.gov/chapters/Jun09_Ch02.pdf

6. Devers, K. and Berenson, R. (2009) Can Accountable Care Organizations Improve the Value of Health Care by Solving the Cost and Quality Quandaries? *Robert Wood Johnson Foundation.*

Summary: The authors survey the potential of ACOs for managing patients' continuum of care across different institutional settings, better allocation of resources and serving as a framework for improved performance measurement of patient populations. The article concludes that ACOs have the potential to improve quality and reduce costs, but will require years of practice and refinement to reach those goals.
http://www.rwjf.org/qualityequality/product.jsp?id=50609

Evaluation of demonstration projects:

7. Simmons, J. (2010) The Medical Home as Community Effort. *Health Leaders.* (April 2010, pp. 50-51).

Summary: The author looks at the three-year-old Pathways to Health collaborative in Battle Creek, Michigan, an effort that brought together Integrated Health Partners, Battle Creek Health

System and local health plans to create a framework including a patient-centered medical home, value-based purchasing and community buy-in. The article focuses on the development of the ACO, as providers, consumers and health plans met and ultimately formed a leadership team. The article details efforts to retain accurate patient data and implement Plan-Do-Study-Act ideals, while creating a new bundled payment structure. So far, Blue Cross Blue Shield of Michigan reports that hospitalizations "for those conditions that better ambulatory care can prevent" have dropped forty percent.
http://www.healthleadersmedia.com/content/MAG-249300/Quality-The-Medical-Home-as-Community-Effort

8. Kaiser Commission on Medicaid and the Uninsured. (2009) *Community Care of North Carolina: Putting Health Reform Ideas into Practice in Medicaid.*

Summary: This article assesses North Carolina's Community Care of North Carolina program, an enhanced medical home model operated by the state's Medicaid program. The program relies on nonprofit community networks of hospitals, physicians, health departments and social service organizations to manage care, and notes that the program saved roughly $3.3 million in the treatment of asthma patients and $2.1 million in the treatment of diabetes patients between 2000 and 2002, while reducing hospitalizations for both patient groups. In 2006, the program saved the state roughly $150 to $170 million. The article concludes that the practices developed by CCNC show promise as tools to implement health reform national and provide "coordinated, cost effective care to low-income individuals with significant health needs."
http://www.kff.org/medicaid/upload/7899.pdf

9. Nelson, Bryn. (2009) Quality over Quantity. *The Hospitalist.*

Summary: The article considers the role integrated systems have played in inspiring ACOs, and surveys a handful of ACO pilots, including Carilion Clinic in Virginia and Robert Wood Johnson Medical School in New Jersey. The article explores possible ACO frameworks, noting that successful models will include the key concepts of local accountability, shared savings and enhanced performance measurements.
http://www.the-hospitalist.org/details/article/477391/Quality_over_Quantity.html

Other Published Literature

10. CMS Office of Legislation (2010) *Medicare Accountable Care Organizations Shared Savings Program: Preliminary Questions And Answers.*

Summary: The document provides an overview of the ACO Shared Savings Program as established in the 2010 Patient Protection and Affordable Care Act, and explores some of the questions emerging from providers regarding ACO participation, including eligibility for shared savings, quality performance standards and the release of future information from CMS concerning the ACO program.

https://www.cms.gov/OfficeofLegislation/Downloads/AccountableCareOrganization.pdf

11. McClellan, M., McKethan, A.N, Lewis, J.L., Roski, J., and Fisher, E.S. (2010) A National Strategy to Put Accountable Care Into Practice. *Health Affairs.* (29, No. 5: 982-990).

Summary: The authors analyze ACOs in the context of recent health care reform legislation, suggesting that ACOs should have flexibility in terms of design but should broadly be provider-led organizations centered on primary care, with payments linked to quality improvement and cost reduction, and increasingly sophisticated performance measurement. The article discusses the structures of a variety of potential payment models, including partial capitation models integrating flat payments with bonuses and penalties related to performance and cost benchmarks, and "symmetric" payment models that offer providers proportionately larger bonuses as they assume greater accountability for costs. The authors conclude that ACOs may have a modest impact on the transformation of payment models in the short-term, but have the potential to drive clinical and financial transformation in the long run.
http://content.healthaffairs.org/cgi/content/abstract/29/5/982

12. Davis, G. and Rich, J. (2010) Health Care Reform: ACOs and Developments in Coordinated Care Delivery, Shared Savings and Bundled Payments. *McDermott Newsletters*.

Summary: The authors compare ACOs to Physician Hospital Organizations (PHOs), arguing that while PHOs were organized mainly to facilitate managed care contracting, while ACOs aim to better coordinate care as a means to both improve quality and control costs. The article also notes some of the key elements of an effective ACO—including medical homes, networks of specialists, care integration and reimbursement models that reward cost-effective high-value-care, and summarizes the provisions of recent health care reform legislation related to ACOs and bundled payment.
http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/6699b22c-127a-4cf0-a80b-bab7a75767de.cfm

13. Burke, T. and Rosenbaum, S. (2010) Accountable Care Organizations: Implications for Antitrust Policy. *Robert Wood Johnson Foundation*.

Summary: The authors detail the relationship between ACOs and federal antitrust policy. Specifically, the article outlines the emphasis the judiciary system has placed on clinical and financial integration as a prerequisite to joint efforts between providers, and notes that arrangements that do not meet financial integration standards are susceptible to violating antitrust statute. The article summarizes several recent antitrust cases brought by the Federal Trade Commission in the context of clinical integration, with examples of both sustained partnerships and those rejected by the legal system. The article concludes that taken together, the decisions support the enforcement agencies' position that in order to justify anti-competitive practices, partnerships between providers must demonstrate collective effort to improve quality and control costs beyond what would have been achieved independently.
http://www.rwjf.org/qualityequality/product.jsp?id=57509

14. Fader, Henry C. (2010) Are Accountable Care Organizations in Your Vocabulary? *Pepper Hamilton, LLP.*

Summary: The author details the legal framework for structuring an ACO, arguing that the entity will require a separate administrative staff that is separate from both the hospital and

AMERICAN HOSPITAL ASSOCIATION
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TRENDWATCH

Clinical Integration – The Key to Real Reform

Regardless of what legislation ultimately passes Congress, many policymakers recognize that systemic changes are needed in how health care is delivered in the United States. Anything less than systemic change may alter the health care system around the edges, but will not achieve the meaningful reform that expands coverage, improves quality and care coordination, rewards effective and efficient care, promotes innovation, and helps control cost. And as the AHA's *Health for Life: Better Health, Better Health Care* initiative has described,[1] achieving greater clinical integration in care delivery is essential to the system change needed to achieve these goals.

Some hospitals already are using a broad range of approaches to integrating more closely with physicians and other health care providers. Clinical integration spans the spectrum from initiatives aimed at achieving greater coordination around a single clinical condition or procedure to fully-integrated hospital systems with closed staffs consisting entirely of employed physicians.

Hospitals seeking greater clinical integration first need to overcome the legal hurdles presented by the antitrust, Stark, Civil Monetary Penalty and anti-kickback laws and the Internal Revenue Code. [See page 11 for a chart of barriers to clinical integration.] The case studies discussed here demonstrate the range of clinically-integrated hospital initiatives in existence today and illustrate how arduous and challenging the legal barriers can be. While some of these barriers to clinical integration are surmountable, they can force hospitals and physicians to spend substantial time and expense in implementing solutions.

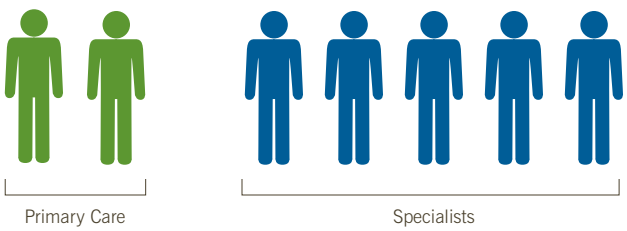
Clinical integration can improve the quality and efficiency of our health care system; however, current legal barriers frustrate reform efforts. The nation needs laws and regulations that encourage or at least do not impede our progress in improving care and care delivery for patients.

The Growing Importance of Clinical Integration

The U.S. health care delivery system is fragmented in several significant ways. First, most office-based physicians continue to practice in solo or small groups.[2] Moreover, to the extent that physicians are moving to larger practices, it is generally to form single specialty practices, and not the multi-specialty groups that are best able to support care coordination.[3] A study of Medicare claims from 2000–2002 found that

Medicare patients see a multitude of physicians.

Chart 1: Average Number of Physicians Medicare Beneficiaries Visit Annually

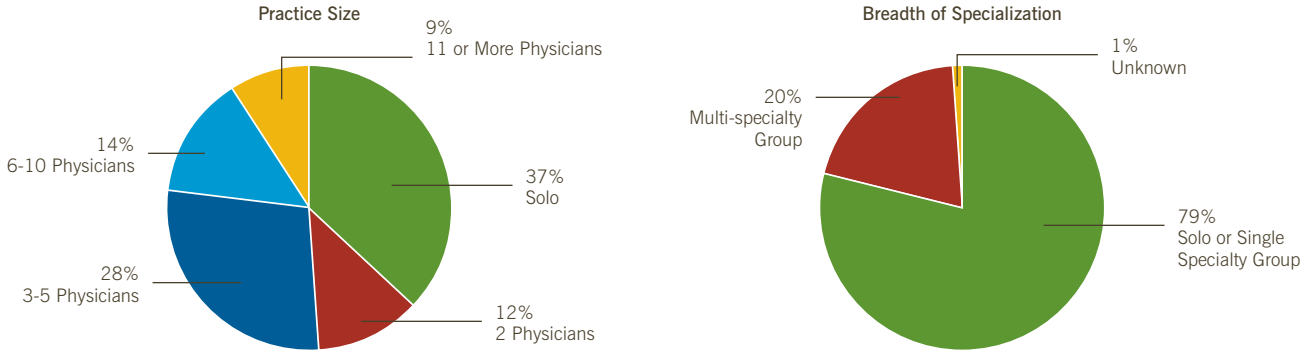


Source: Pham, H, Schrag, D., et al. (2007). Care Patterns in Medicare and Their Implications for Pay for Performance. *The New England Journal of Medicine*, 356; 1130-1139.

American Hospital Association

Office-based physicians continue to practice in solo or small groups.

Chart 2: Distribution of Office-based Physicians



Source: Characteristics of office-based physicians and their practices: United States, 2005–2006. *Vital and Health Statistics*. 13:1-34, Apr. 2008. Available at <http://www.cdc.gov/nchs/data/series/sr_13/sr13_166.pdf >

each year the typical Medicare beneficiary saw a median of two primary care physicians and five specialists, collectively working in four different practice settings.[4] Typical patients with multiple chronic conditions saw as many as three primary care physicians and eight specialists in seven different settings.[5] A study by the Robert Wood Johnson Foundation found that for every 100 Medicare patients treated, each primary care physician would typically have to communicate with 99 physicians in 53 practices to coordinate care.[6]

Second, the common model of hospital-physician relationships, as reflected in the organized medical staff, does not assure the optimal level of care coordination between a hospital and its independent physicians.[7] In this common model, physicians use hospital facilities and rely on hospital staff to provide their services, but the medical staff is not employed by the hospital. As a result, hospitals and physicians have limited tools they can use to positively influence each other's practice patterns to achieve optimal patient outcomes, especially since most forms of economic incentives may run afoul of Stark, anti-kickback and the Civil Money Penalty laws that apply to Medicare and Medicaid patients. [See chart of potential barriers to clinical integration.]

Third, care is fragmented because patients receive services in several locations, including freestanding ambulatory sites and post-acute settings or their homes. Some of these settings may be affiliated with a hospital, while others may compete or offer complementary services. This fragmented care can adversely impact quality and efficiency. Without adequate care coordination, patients are more likely to receive duplicative diagnostic testing, have adverse prescription drug interactions and have conflicting care plans. These scenarios add to the challenges patients face in navigating the health care delivery system at a time when they are most vulnerable. Fragmentation also frustrates attempts by hospitals and physicians to improve the quality and efficiency of care. Physicians in small groups are less likely to be able to afford the information technology to implement electronic heath records and similar technologies. They also will have more difficulty in sharing "best practices" and accessing peer data for use as benchmarks.

What Is Clinical Integration?

Clinicians and policymakers have drafted several definitions of clinical integration. The definitions generally focus on efforts that involve collaboration among different health care providers and sites to ensure higher quality, better coordinated and more efficient services for patients. In the context of antitrust, the Federal Trade Commission (FTC) and Department of Justice (DOJ) have discussed clinical integration in considering when joint negotiations by health care providers with health plans would be permissible. Traditionally, providers had to demonstrate they were financially integrated (e.g., furnishing services under capitation) in order to come together and jointly negotiate with health plans. In addition to financial integration, the FTC and DOJ also now take clinical integration (nonfinancial integration) into account in examining whether providers may jointly negotiate with health plans.

Some Definitions of Clinical Integration

"Clinical integration facilitates the coordination of patient care across conditions, providers, settings, and time in order to achieve care that is safe, timely, effective, efficient, equitable, and patient-focused. To achieve clinical integration our nation's health care system needs to promote changes in provider culture, redesign payment methods and incentives, and modernize federal laws."

Health for Life Expert Advisory Group on Clinical Integration

"[Clinical] integration can be evidenced by [a physician] network implementing an active and ongoing program to evaluate and modify practice patterns by the network's physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. This program may include: (1) establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care; (2) selectively choosing network physicians who are likely to further these efficiency objectives; and (3) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies."

Department of Justice and Federal Trade Commission, *Statements of Antitrust Enforcement Policy in Health Care*, Statement 8 (1996)

"Clinical integration is the extent to which patient care services are coordinated across people, functions, activities, and sites over time so as to maximize the value of services delivered to patients."

Stephen M. Shortell, Robin R. Gillies, David A. Anderson, *Remaking Health Care in America*, 2000

"In essence, clinical integration involves providers working together in an interdependent fashion so that they can pool infrastructure and resources, and develop, implement and monitor protocols, "best practices," and various other organized processes that can enable them to furnish higher quality care in a more efficient manner than they likely could achieve working independently. Such programs can enable primary care physicians and specialists of all kinds to work more closely with each other in a coordinated fashion."

Guidelines for Clinical Integration, a Working Paper Prepared for AHA by Hogan & Hartson, LLP, April 2007

IT Infrastructure Is Required

A key component to most clinical integration strategies involves greater information sharing across providers. In 2009 Congress authorized $36 billion to fund an electronic health information infrastructure when it passed the *Health Information Technology for Economy and Clinical Health* (HITECH) *Act*, as part of the stimulus package. Among other things, beginning in 2011 HITECH will provide additional funding through Medicare and Medicaid to providers who are "meaningful users" of electronic health records.

Under a limited exception to the Stark and anti-kickback laws and guidance from the Internal Revenue Service (IRS), hospitals are able to assist physicians in developing electronic health records. Additional flexibility would be helpful; the exception does not allow hospitals to share hardware or completely subsidize connectivity and software. Despite these limitations, systems like Sutter Health have successfully expanded use

"from the field"

"Most physicians are in small practices. No matter what happens in health care reform, that won't change any time soon. Clinical integration connects the dots and enables these physicians to meet the needs of the community."

Lee Sacks, M.D., President, Advocate Physician Partners

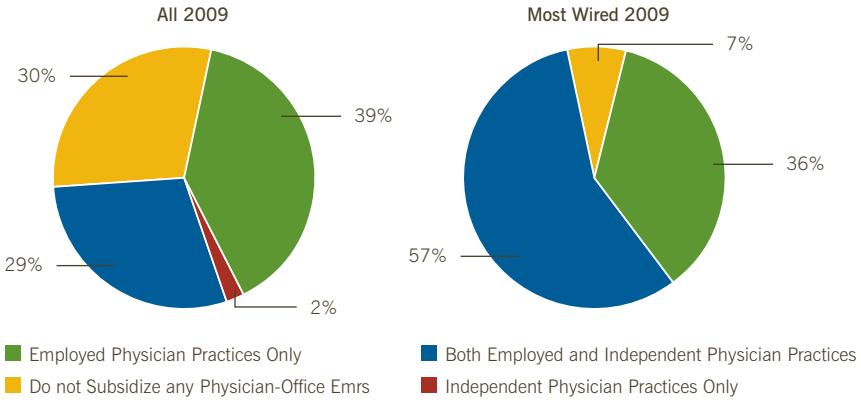
of information technology as a result of the lowered regulatory barrier.

While limited regulatory relief helped increase IT sharing, as Chart 3 demonstrates, there is still a huge opportunity for hospitals and physicians to establish the type of information sharing that will support greater clinical integration.

Other steps that could facilitate information sharing include development of clinical guidelines and other measures to help caregivers assess their effectiveness in delivering appropriate care.

Hospital subsidies for physician office electronic medical records (EMRs).

Chart 3: The Percentage of Respondents in Each Benchmark Group that Subsidize Physician-office EMRs



Source: *Hospitals & Health Networks'* Most Wired Survey and Benchmarking Study, March 2009

Sutter Health – Using Information Technology for Clinical Integration

Sutter Health has a long-standing commitment to investing in innovation that advances clinical integration across the care continuum. The health system utilizes fully integrated MIDAS software across its 25 acute care facilities to consistently report and measure quality indicators as well as standardize case and utilization management functions. Sutter also designed a fully integrated electronic health record (EHR) system (from the Epic platform) that facilitates care coordination across care settings and geographic locations. For example, EHR technology is available in Sutter's retail urgent care clinics – Sutter Express Care – that provides timely information to primary care physicians that their patients were seen and addresses care follow-up that might be needed. Similarly, Sutter offers remote connectivity to EHR data for community physicians who have referral relationships. Finally, the Sutter-affiliated Palo Alto Medical Foundation is researching the use of online services integrated with the electronic health record to further partner with and empower chronically ill patients to take an active role in managing their health.

Using Payment Reforms to Promote Integration

Policymakers increasingly are looking to payment reforms as a means to promote greater clinical integration. The Medicare Payment Advisory Commission's (MedPAC) 2008 *Report to Congress* recommended replacing the current Medicare fee-for-service system with one that "would pay for care that spans across provider types and time (encompassing multiple patient visits and procedures) and would hold providers accountable for the quality of care and the resources used to provide it. This new direction would create payment system incentives for providers that reward value and encourage closer provider integration, which would maximize the potential for tools such as pay for performance and resource management to improve quality and efficiency."[8]

MedPAC suggested three approaches to help achieve these goals –medical homes, bundled payments and "accountable care organizations (ACOs)." These suggestions are not entirely new; the Centers for Medicare & Medicaid Services (CMS) is conducting several Medicare demonstration projects to test payment and delivery reforms that rely on enhanced clinical integration. It is important to note that these projects have required waiver of various regulatory restrictions that otherwise would have prevented their implementation.

Interest in payment reforms to promote greater clinical integration has

increased over the past year, and is seen by many as integral to "bending the cost curve" to ensure meaningful and long-term health care reform.[9] In late December 2009, a group of freshmen senators sought to advance clinical integration by exploring ways to lower regulatory barriers. In a letter to the heads of DOJ's Antitrust Division and the FTC, the senators asked the agencies to issue "clear and accessible guidelines on forming collaborative care models."[10] In a separate letter, Sen. Max Baucus (D-MT) joined the senators in asking the Government Accountability Office to study and report on federal and state laws "that may impede or discourage" collaborative relationships among caregivers, including Stark and anti-kickback laws.[11]

National health care reform proposals have called for demonstrations involving new patient care models, all of which involve greater clinical integration. For example, lawmakers have proposed a three-year pilot program on ACOs.

States are embarking on a similar path. Massachusetts' Special Commission on the Health Care Payment System recently recommended that global payments with adjustments to reward accessible and high quality care become the predominant form of payment to providers. Such care would be provided through ACOs "composed of hospitals, physicians, and/or other clinician and non-clinician providers working as a team to manage both the provision and coordination of care for the full range of services that patients are expected to need."[12]

A demonstration project at Continuum Health Partners (CHP) in New York City offers another example of the type of cost and quality improvements that can be achieved by aligning hospitals and physicians through appropriate financial incentives. Preliminary results of CHP's initial gainsharing program involving commercial patients (implemented before the Medicare demonstration was approved) indicated that participating physicians were able to achieve cost-savings of $900 per admission, twice as much as physicians who did not participate in the program.

Continuum's Medicare Gainsharing Demonstration Project

Medicare currently is conducting several demonstration projects designed to test whether gainsharing – whereby a hospital shares some of the cost savings from increased efficiency with its physicians – can align incentives between hospitals and physicians to lead to improved quality and efficiency. One of these is being undertaken at two hospitals of Continuum Health Partners, Inc. (CHP), a six-hospital health care system in New York City. (Medical staff at these two demonstration hospitals includes both employed and independent physicians.)

ALIGNING INCENTIVES

A starting point in the CHP demonstration was the realization that not only is there a tremendous variation in resource use among providers in different parts of the country – which has been widely-recognized – but that even within a single hospital there can be a wide variation in costs for treating the same severity-adjusted cases. Thus, CHP estimated that the cost variations for inpatient care for commercial patients of all its physicians eligible for a pay-for-performance program in 2007 was $100 million. This was the difference between the amount spent on patients treated by physicians at the 25th percentile and those at the 75th percentile. This suggested the opportunity for very significant savings that, if shared, could be used to substantially align the incentives of CHP and its physicians.

CHP's program provides an incentive of up to 25% of the third-party payment to the "responsible physician" for each inpatient, to be determined based on improvement (compared to performance the prior year) and relative performance (compared to a "best practice norm" derived from peer providers in the CHP system). Among other things, to be eligible for incentive payments, physicians must meet or exceed certain quality thresholds, such as Medicare Core Measures, readmission rates, unplanned return to the operating room and timely completion of medical records. All data used for the program is both case-mix and severity-of-illness adjusted.

from the field

"Crucial to clinical integration is giving physicians a real involvement in decision-making at the hospital. Physicians must be able to work with hospital administration to identify a shared set of goals for the enterprise – what do they want to accomplish together – and then they can together develop tactics to achieve those goals."

Nick Wolter, M.D., CEO, Billings Clinic

TACKLING REGULATORY HURDLES

The program began in 2006 with only commercial patients because of restrictions under the civil monetary penalties, anti-kickback and Stark laws that would apply to Medicare and Medicaid patients. CMS granted a waiver to these restrictions starting in October 2008 as part of the Medicare Hospital Gainsharing Demonstration Project under Section 5007 of the *Deficit Reduction Act of 2005*. Congress explicitly granted CMS the authority to make such waivers after a federal court had ruled that a similar demonstration project initiated several years earlier could not proceed without a waiver of the gainsharing prohibition. (*Robert Wood Johnson University Hospital, Inc. v. Thompson*, 2004 U.S. Dist. LEXIS 6893 (D.N.J. 2004))

Administrators involved with the program believe that it has great potential for savings, and that it could be replicated at other facilities nationwide. They caution that such efforts, in addition to waivers, require not only IT infrastructure, but dedicated work with physicians to demonstrate that by modifying practice patterns quality and efficiency can be improved. Gainsharing not only gives physicians an incentive to change their own practices, but also to identify ways in which the hospital can streamline its operations.

ACHIEVING POSITIVE RESULTS

CHP's initial data indicate that the average incentive for physicians was $96 on a medical case and $140 on a surgical case. During the first two years of the program, CHP had a savings of approximately $900 (a 12.5% decrease) per case for participating physicians. While some of the savings may be attributed to other hospital initiatives, a large portion can be attributed to the gainsharing initiative. A key component of this and similar programs is that the providers – as opposed to the government or payer – is responsible for allocating revenues and therefore assuring that incentives are appropriately aligned and that the efficiencies undertaken do not reduce the quality of the care provided to patients.

To position themselves for this new payment and competitive environment, hospitals are considering how they can increase the extent of their clinical integration, particularly with physicians on their medical staff. Clinical integration cannot be achieved instantly. It requires leadership from both hospitals and physicians, development of an appropriate culture, organizational changes, support from payers, and a great deal of effort. It also requires sufficient infrastructure, which includes not only hard assets such as information technology, but also staff such as advanced practice nurses who can work with physicians – and their staff – to develop and implement improvements and greater coordination in clinical processes.

The Clinical Integration Spectrum

Hospital efforts at clinical integration span a broad spectrum of arrangements. At one end are targeted initiatives by a hospital and a subset of its voluntary medical staff to address a particular clinical condition or procedure. For example, a hospital and its orthopedic surgeons work together on an initiative to reduce the costs of knee or hip implants by developing specific protocols and concentrate implant purchases from a smaller number of manufacturers. At the other end of the spectrum are health systems in which physician groups and hospitals are under the same ownership or are otherwise fully integrated economically. There are arrangements at all points along the continuum. For example, hospitals in the "middle" of the spectrum would include those who employ a substantial number, but far less than all, of their physicians. Another example in the middle of the continuum would be a hospital that has a very active physician-hospital organization (PHO) that includes independent (non-employed) physicians who are involved in an extensive clinical integration program that covers a wide range of initiatives and involves joint negotiations with health plans.

While some hospitals and physicians have long-established clinical integration approaches, others are just embarking in this area, often starting with more limited initiatives with the goal of expanding if these prove successful. Moreover, hospitals vary with respect to the extent to which they are integrated with other sites of service, such as home health care, post-acute care, long term care and hospice, as well as integration with payer functions through an affiliated or wholly-owned health plan.

Efforts at clinical integration span a broad spectrum.

Chart 4: Clinical Integration Spectrum

Less Integrated — More Integrated

Bundled payment for single episode of care	Bundled payment for chronic care management	Clinically Integrated PHO	Medical staff includes both employed and independent physicians	Medical Staff includes only (or almost only) fully-employed physicians
• Fairview Health (Minneapolis) • Geisinger Proven Care Program for Coronary Artery Bypass Graft Surgery (Danville, PA)	• Fairview Health (Minneapolis) • Sutter Health (California) • Park Nicollet Health (Minneapolis)	• Advocate Health Care (Chicago) • Tri-State Health (Maryland)	• Presbyterian Health (Albuquerque) • Virginia Mason Hospital (Seattle) • Geisinger Hospital (Danville, PA) • Intermoutain Health Care (Utah)	• Cleveland Clinic (Ohio) • Billings Clinic (Montana) • Kaiser Permanente (multi-state)

Source: American Hospital Association

Fairview Health Services: Working with Four Different Physician Models

"The only way we can change the way care is provided is by working closely with the people who provide the care."

"Regardless of what health care package passes, we need to change the way we pay for the care that is provided. And the direction that we are going at Fairview will make sense no matter what payment model is adopted."

Mark Eustis, CEO, Fairview Health Services

Fairview Health Services (FHS), which includes a major academic medical center in Minneapolis, has embarked on a number of innovations to improve care, such as, creating a "health home" to fundamentally change how primary care is furnished, developing a single electronic health record for the entire continuum of health services and expanding the use of virtual medicine. One innovation that focuses on greater clinical integration is the development of 12 "care packages," each covering a set of clinical best practices for a particular clinical condition. These packages will create more consistent, high quality care, and also will involve a change to the payment system so that providers are paid based on a single fee covering the entire package of services, instead of being paid for each test or visit. Care packages range from chronic conditions (low back pain, diabetes, migraine) to specific medical care (prenatal care) or surgical procedures (total knee replacement). Some of the packages are being developed at the request of specific employers, such as Target or 3M.

In implementing these innovations, FHS must collaborate with physicians who practice in four different arrangements with FHS:

- About 500 physicians, mostly primary care physicians, are employed by FHS
- About 700 physicians, mostly specialists, are in the University of Minnesota faculty practice plan
- About 1,000 physicians are in a PHO (some of whom are also employed by FHS or are in the faculty practice plan)
- About 1,500 physicians are in separate independent practices

These arrangements present different challenges and opportunities. For example, to the extent the care packages involve financial incentives, they can raise gainsharing, Stark or anti-kickback issues that may be difficult to address for the physicians in independent practices (at least for Medicare and Medicaid patients), but are unlikely to present issues for the employed physicians. Similarly, antitrust should not be an issue if FHS wishes to negotiate payments on behalf of its employed physicians, but likely would preclude such negotiations on behalf of the faculty practice, independent or PHO physicians, unless the arrangement involves the requisite financial or clinical integration. Navigating the different rules that apply to different physicians depending upon the nature of their relationship to FHS can impede system- wide innovations that otherwise might be applied to the entire FHS medical staff.

Presbyterian Healthcare Services: An Affiliated Large Multi-specialty Group Practice and Health Plan

"Our medical group provides us with an opportunity to innovate in providing care."
Jim Hinton, President and CEO, Presbyterian Healthcare Services

Presbyterian Healthcare Services (PHS), headquartered in Albuquerque, New Mexico, is using its affiliated Presbyterian Medical Group (PMG) of 600 physicians and practitioners, eight hospitals across the state, and its affiliated Presbyterian Health Plan that serves 450,000 members statewide, to explore new ways to deliver health care.

While there are roughly the same number of independent physicians on the medical staff as in the employed medical group, PMG offers an advantageous environment to innovate to increase quality and efficiency. For example, Presbyterian is developing a pilot program to test a Medical Home initiative that will require physicians to perform many services for which they would not be separately paid under the typical fee schedule. This approach would be difficult to implement with independent physicians who rely on fee-for-service reimbursement. This is not an obstacle, however, for physicians on salary in PMG, who also can be rewarded through payments that take into account the quality of patient outcomes and efficiency of services.

Once Presbyterian gains experience with the Medical Home, it can then roll out the concept to its independent physicians. In taking this next step, PHS can use its health plan to structure quality performance-based payments to participating providers.

Many hospitals shed affiliated health plans that they developed in the 1990s. But Presbyterian believes that the experience that it is obtaining with its affiliated plan may serve it well to the extent health care reform encourages the development of "accountable care organizations" that will be responsible for providing a broad range of healthcare services to a defined set of patients.

Employed physicians and an affiliated health plan give Presbyterian more tools and greater flexibility to align incentives among the hospital and the provider community.

Virginia Mason: Mostly Fully-employed Medical Staff

Virginia Mason Medical Center (VMMC) traces its roots to eight physicians who formed a group practice modeled after the Mayo Clinic and, in 1920, built an 80-bed hospital in Seattle. Today more than 440 physicians at Virginia Mason are employed by VMMC and account for about two-thirds of the hospital's admissions. The remaining admissions are primarily from two other fully-integrated group practices, the Pacific Medical Centers (a 140-physician multi-specialty group) and Group Health Cooperative, a staff-model HMO.

Because a large majority of the medical staff is VMMC employees, it is easier to align the physician and hospital interests. This has enabled VMMC to embark on an ambitious system-wide program to change the way it delivers care. Modeled on the Toyota Production System, it is called the "Virginia Mason Production System" (VMPS) and began in 2001. Utilizing VMPS, staff members make measurable improvements in safety, quality, service, staff and patient satisfaction, and cost performance.

VMPS uses a variety of strategies to improve efficiency, ranging from small-scale ideas tested and implemented immediately to long-range planning that redesigns new spaces and processes. The strategies involve "kaizen" or continuous improvement activities, which are based on the view that staff who do the work know what the problems are and how best to find solutions. VMPS embraces the view that by measuring and standardizing performance, it is possible to substantially improve efficiency and quality. While some are skeptical that this approach – which is more readily identified with automotive assembly lines – can be adapted to deal with individualized patient care, VMMC is able to try it because so many of the medical staff are working under the integrated management of hospital and physician leaders.

VMPS initiatives have included the following:

- A **Patient Safety Alert System** to ensure situations that are likely to harm a patient are reported and investigated immediately, with complete commitment of all employees, including hospital staff, physicians, and senior medical leadership. The result has been an increase in patient safety and a decrease in medical claims.
- **One-stop Care for Cancer Patients**, which includes a redesigned cancer center to eliminate the need for patients to travel long distances in the hospital to obtain chemotherapy.
- **Evidence-Based "Bundles"** to improve care. VMMC had 34 cases of ventilator-associated pneumonia (VAP) in 2002. After implementing the ventilator bundle (a set of specific steps proven to reduce the incidence of VAP) in 2004, Virginia Mason had only four cases. Compliance with bundle elements remains at or near 100 percent, with 0-3 VAP cases/year for the past two years.

Due to an overwhelming number of requests for Virginia Mason staff to share their knowledge in applying these principles to health care, VMMC established the Virginia Mason Institute to educate and train other health care providers in VMPS management techniques.

Advocate Physician Partners: A Clinically Integrated PHO

"A key component to a successful program is to invest in physician leadership. At the end of the day, the doctors have to drive it – surrounded and supported by good management."

Lee Sacks, M.D., President, Advocate Physician Partners

In metro Chicago, Advocate Health Care is the largest health system with eight acute hospitals and over 5,200 physicians on its medical staff. Through the Clinical Integration Program of Advocate Physician Partners (APP), the system collaborates with 3,400 of these physicians (of whom about 800 are employed by the system or one of its affiliates) in one of the largest clinical integration efforts in the nation.

Advocate's program evolved from efforts by its PHOs to provide care on a capitated basis to HMOs. Advocate currently is implementing 37 key clinical initiatives that address clinical outcomes, efficiency, medical and technological infrastructure, patient safety and patient satisfaction. Physicians receive feedback in the form of quarterly "report cards" that are the basis of financial incentives which reflect performance both individually and at the PHO level. In 2008, participating Advocate physicians earned $28 million in incentive payments, or about $9,000 per physician. Advocate has achieved significant clinical and efficiency results, which it summarizes in an annual "Value Report" that is given to employers and payers, and is available at www.advocatehealth.com. Every major health plan in the Chicago area contracts with APP and participates in its clinical integration program.

Implementing the clinical integration program has required substantial resources over an extended time period. Advocate estimates that the program currently employs 24 dedicated FTEs, and also piggybacks on about $100 million in investments in IT infrastructure that Advocate has made in electronic health records, an eICU, and a computerized patient order entry system. In a new initiative announced in early September, APP will contribute an additional $15,000 to each of its physicians who agreed to install the ambulatory electronic record selected by APP. This contribution, along with money from the federal stimulus package, should help ensure that most APP physicians use a common electronic medical record system in their office. This should enable APP to more efficiently coordinate care.

The clinical integration program had to withstand a multi-year antitrust investigation by the Federal Trade Commission that ultimately declined to challenge Advocate's joint negotiations with health plans on behalf of its independent physicians. In July 2007, FTC Commissioner Pamela Jones Harbour spent an entire day visiting Advocate to gain a better understanding of its program, and afterwards reported back "that clinical integration, when done right, has tremendous potential to create efficiencies and improve health care quality."[13]

Legal Barriers to Clinical Integration

Hospitals face a number of legal and regulatory barriers as they seek to improve clinical integration with their physician staffs. Perhaps the biggest barrier to innovative arrangements are the provisions of the Civil Monetary Penalty statute that prohibit gainsharing, and the Stark and anti-kickback laws – as they apply to Medicare and Medicaid patients; in some states, there may be similar state prohibitions that apply to other patients. These laws are aimed at curbing arrangements that involve financial incentives to providers that could result in either over-utilization, under-utilization (i.e., the withholding of necessary items or services), or referrals that are based on considerations other than what might be in the best interest of the patient. While well intended, the statutes are either broadly written or interpreted so as to also prohibit – or create uncertainties about – a broad range of benign arrangements that could better align hospitals and physicians and pose little or no potential risk of abuse.

Providers also have expressed reluctance to engage in clinical integration because of perceived antitrust risks. The antitrust concern arises when providers who are in independent practices and offer competing items or services jointly negotiate with payers. But if such joint negotiations are needed for the clinical integration to succeed, and the providers collectively lack market power, the effort should survive antitrust scrutiny. Nevertheless, because the antitrust laws do not provide bright-line rules in this area, uncertainty about whether their clinical integration efforts would attract antitrust review has deterred some hospitals and physicians from embarking on innovative arrangements.

Other legal concerns can arise from IRS provisions applying to tax-exempt organizations, state corporate practice of medicine statutes, state insurance regulations and malpractice litigation. See Chart 5.

Conclusion

While there are divergent views about the role of government in health care reform, there is a growing consensus that there is a need for significant health care delivery change, and that such change must involve increased clinical integration among health care providers. Clinical integration holds the promise of greater quality and improved efficiency in delivering patient-centered care. Such efforts are likely to be particularly important if, as is widely expected, government and private health plans change to payment methodologies that put a premium on the ability of providers to collaborate effectively.

There is no single path to clinical integration. Rather, hospitals and physicians have embarked on clinical integration in a variety of ways, and are likely to develop many more approaches in the future. These efforts have required hard work, development of a culture that facilitates alignment, investment in infrastructure, support from health plans and leadership on the part of both the hospital and physicians. Some have proceeded despite legal and regulatory barriers that have made it more difficult for hospitals and physicians to collaborate. The AHA and others have urged that steps be taken to reduce these barriers, including changes to anti-kickback, Stark and Civil Money Penalty prohibitions, as well as greater guidance from the antitrust agencies and the IRS regarding their review of clinical integration initiatives. Such regulatory reforms are important to ensure that hospitals and other health care providers can engage in the type of clinical collaborations that can significantly improve U.S. health care.

“ ” from the field

“To end the current fragmentation, waste and complexity, physicians and other care providers should be rewarded, through financial and nonfinancial incentives, to band together into traditional or virtual organizations that can provide the support they need to practice 21st century health care.”

The Commonwealth Fund, “A High Performance Health System for the United States” (November 2007)

A look at the legal barriers to clinical integration and proposed solutions.

Chart 5: Legal Barriers and Proposed Solutions

Law	What Is Prohibited?	The Concern Behind the Law	Unintended Consequences	How to Address?
Antitrust (Sherman Act §1)	Joint negotiations by providers unless ancillary to financial or clinical integration; agreements that give health care provider market power	Providers will enter into agreements that either are nothing more than price-fixing, or which give them market power so they can raise prices above competitive levels	Deters providers from entering into procompetitive, innovative arrangements because they are uncertain about antitrust consequences	Guidance from antitrust enforcers to clarify when arrangements will raise serious issues. DOJ indicated it will begin a review of guidance in Feb. 2010.
Ethics in Patient Referral Act ("Stark Law")	Referrals of Medicare patients by physicians for certain designated health services to entities with which the physician has a financial relationship (ownership or compensation)	Physicians will have financial incentive to refer patients for unnecessary services or to choose providers based on financial reward and not the patient's best interest	Arrangements to improve patient care are banned when payments tied to achievements in quality and efficiency vary based on services ordered instead of resting only on hours worked	Congress should remove compensation arrangements from the definition of "financial relationships" subject to the law. They would continue to be regulated by other laws.
Anti-kickback Law	Payments to induce Medicare or Medicaid patient referrals or ordering covered goods or services	Physicians will have financial incentive to refer patients for unnecessary services or to choose providers based on financial reward and not the patient's best interest	Creates uncertainty concerning arrangements where physicians are rewarded for treating patients using evidence-based clinical protocols	Congress should create a safe harbor for clinical integration programs
Civil Monetary Penalty	Payments from a hospital that directly or indirectly induce physician to reduce or limit services to Medicare or Medicaid patients	Physicians will have incentive to reduce the provision of necessary medical services	As interpreted by the Office of Inspector General (OIG), the law prohibits any incentive that may result in a reduction in care (including less expensive products)…even if the result is an improvement in the quality of care	The CMP law should be changed to make clear it applies only to the reduction or withholding of medically necessary services
IRS Tax-exempt Laws	Use of charitable assets for the private benefit of any individual or entity	Assets that are intended for the public benefit are used to benefit any private individual (e.g., a physician)	Uncertainty about how IRS will view payments to physicians in a clinical integration program is a significant deterrent to the teamwork needed for clinical integration	IRS should issue guidance providing explicit examples of how it would apply the rules to physician payments in clinical integration programs
State Corporate Practice of Medicine	Employment of physicians by corporations	Physician's professional judgment would be inappropriately constrained by corporate entity	May require cumbersome organizational structures that add unnecessary cost and decrease flexibility to achieve clinical integration	State laws should allow employment in clinical integration programs
State Insurance Regulation	Entities taking on role of insurers without adequate capitalization and regulatory supervision	Ensure adequate capital to meet obligations to insured, including payment to providers, and establish consumer protections	Bundled payment or similar approaches with one payment shared among providers may inappropriately be treated as subject to solvency requirements for insurers	State insurance regulation should clearly distinguish between the risk carried by insurers and the non-insurance risk of a shared or partial risk payment arrangement
Medical Liability	Health care that falls below the standard of care and causes patient harm	Provide compensation to injured patients and deter unsafe practices	Liability concerns result in defensive medicine and can impede adoption of evidence-based clinical protocols	Establish administrative compensation system and protection for physicians and providers following clinical guidelines

- Other than removing legal and regulatory barriers, how can policymakers encourage doctors, hospitals and other caregivers to work together to provide more coordinated care to patients?
- Is greater financial, technical or other support required to facilitate information sharing among doctors, hospitals and other caregivers that are engaged in efforts to better coordinate care and/or track the results of coordinated care?
- How can we incorporate learnings from clinical integration models underway in the private-sector with those from government-initiated clinical integration pilot projects to help accelerate the pace of change to more coordinated care?

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Getting More *Reform* from Health Reform

Five Barriers to Clinical Integration in Hospitals (and what to do about them)

What is Clinical Integration – and Why is it Important to Health Reform?

At its heart, clinical integration is teamwork: hospitals, doctors, nurses and other caregivers working together to make sure patients get the right care, at the right time, in the right place. Clinical integration can take many forms. In some, different providers may collaborate to tackle a single condition, like diabetes. In others, the hospital, doctors and other caregivers may function as a single entity, working together to provide seamless care to all patients.

Regardless of its form, clinical integration relies on teamwork. That is different from the way most health care is delivered today, where providers tend to work separately, in their own "silos" of expertise. Physicians typically work alone or in group practices; physical therapists, social workers and home health providers often work on their own as well. And different facilities tend to work separately, such as acute-care hospitals and long-term care facilities.

Clinical integration is important. Meaningful health care reform, and the quality and efficency improvements it promises, is built around the teamwork clinical integration creates. For example, various legislative proposals would create accountable care organizations, as well as a national pilot program on payment bundling. Such proposals rely on clinical integration, and share the same goals as clinical integration: creating better patient outcomes by delivering higher quality care, and making the medical system less expensive, more efficient and easier to navigate for patients and providers alike.

Hospitals are trying to spur this kind of teamwork, but regulatory barriers stand in the way. The following pages describe them and the proposals supported by hospitals that can promote teamwork by knocking down these barriers to clinical integration.

What are the Barriers … What is the Solution?

The barriers to clinical integration range from confusing antitrust policies to outdated rules governing relationships between hospitals, doctors and other caregivers. Even Internal Revenue Service (IRS) rules can be a barrier because they are applied by an agency largely removed from health care delivery and how it is evolving.

There are solutions. They range from creating user-friendly antitrust guidelines and safe harbors, to providing clear congressional direction on existing rules that promote instead of hinder clinical integration. In one instance, simply refocusing a law on its original intent could solve the problem. For the IRS, the solution involves issuing guidance compatible with these other regulatory changes.

American Hospital Association

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Getting More *Reform* from Health Reform

Five Barriers to Clinical Integration in Hospitals (and what to do about them)

ANTITRUST

What is Antitrust and Why is it a Barrier?

The antitrust laws govern our nation's policies on competition; their purpose is to protect competition and ensure a level playing field for consumers. The U.S. Department of Justice's (DOJ) Antitrust Division and the Federal Trade Commission (FTC) share authority to interpret and apply antitrust laws, and there are serious civil and criminal penalties for violating these laws … even if the violation is unintentional.

Federal antitrust agencies have traditionally been skeptical of clinical integration because there typically is no conventional shared financial risk. In other words, no "up front" money is at stake; clinical integration seeks to improve care coordination and quality by encouraging caregivers to work together to meet specific practice guidelines and/or quality standards … and rewards them when these goals are achieved. The ability to negotiate together for the payment that will cover the services offered through the clinical integration program is often an essential ingredient in its success.

Recently, the antitrust agencies have become more receptive to clinical integration. However, instead of simply issuing guidelines to help caregivers better understand how the laws would be applied, the FTC has issued lengthy staff opinion letters that are expressly limited to the facts contained in the opinion letter and that warn the "Commission is not bound by the staff opinion and reserves the right to rescind it at a later time." The result: caregivers can neither readily understand nor completely rely on those opinion letters.

What's the Solution?

The best solution is to issue user-friendly, officially backed guidance that clearly explains to caregivers what issues they must resolve to embark on a clinical integration program without violating antitrust laws. DOJ and FTC have issued such user-friendly and officially backed guidance in the past, and, in their 1996 *Statements of Antitrust Enforcement Policy in Health Care,* promised to do so again when warranted. The Statements can be found at http://www.usdoj.gov/ atr/public/guidelines/ 0000.htm.

We believe this approach is now warranted, and that Congress should instruct the antitrust agencies to issue guidance that clearly explains how caregivers can navigate the antitrust laws to create clinical integration programs.

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Getting More *Reform* from Health Reform

Five Barriers to Clinical Integration in Hospitals (and what to do about them)

THE ETHICS IN PATIENT REFERRALS ACT (THE STARK LAW)*

What is this Law and Why is it a Barrier?

Usually called the Stark law, it was originally enacted to ban doctors from referring patients to facilities in which the doctor has a financial interest (known as self-referral). However, a tight web of regulations and other prohibitions that have grown up around the law can now ban arrangements designed to encourage hospitals and doctors to team up to improve patient care in a clinical integration program.

The Stark law requires that compensation for health care providers be fixed in advance and paid only for hours worked. As a result, payments that are tied to achievements in quality and efficiency instead of hours worked do not meet the law's strict standards.

That means a hospital or clinic that rewards a doctor, and the doctor who earns the reward, for following protocols that guide the clinical integration program, can be found in violation. For example, a doctor that receives a bonus as part of a clinical integration program that helps patients manage their diabetes according to a well-designed medical protocol, risks being in violation of the Stark law.

The law is so strict that, in order to launch demonstration projects supporting clinical integration, the Centers for Medicare & Medicaid Services (CMS) had to waive the law. Without this waiver, a program in which hospitals shared cost savings with non-employed physicians who participated in a well-designed effort to enhance quality and efficiency would not have been possible.

Those found in violation of the law face severe consequences. In addition to civil penalties, providers can be barred from serving Medicare, Medicaid and other federal program patients for years, effectively shutting down the hospital and ending the doctors' careers.

What's the Solution?

The best solution is to return the Stark law to its original focus of regulating self-referral to physician-owned entities. This could be done by removing compensation arrangements from the definition of "financial relationships" that are subject to the Stark law. These same compensation arrangements would still be regulated, but by other federal laws already on the books, such as anti-kickback and civil money penalty laws, that are better equipped to do so.

** This discussion does not pertain to the "whole hospital exception" to the Stark law that permits doctors to refer when they have an ownership interest in the entire hospital.*

American Hospital Association

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Getting More *Reform* from Health Reform

Five Barriers to Clinical Integration in Hospitals (and what to do about them)

THE CIVIL MONETARY PENALTY LAW

What is the Law and Why is it a Barrier?

The Civil Monetary Penalty (CMP) law prohibits hospitals from rewarding physicians for reducing or withholding services to Medicare or Medicaid patients. The prohibition was established in the 1980s in response to concerns that Medicare patients served under the new prospective payment system for hospitals might not receive the same level of services as other patients.

The Department of Health and Human Services' Office of Inspector General (OIG), however, has taken the CMP law a step further, claiming that the law prohibits *any* incentive that affects a physician's delivery of care. The result: a clinical integration program that, for example, rewards a doctor for following an evidence-based timetable for the administration of beneficial drugs could be in violation of the law.

Those found in violation face severe consequences. Penalties range from $2,000 per patient affected to $50,000 for other types of violations. In addition to civil penalties, providers can be barred from serving Medicare, Medicaid and other federal program patients for years, effectively shutting down the hospital and ending the doctors' careers.

An illustration of how CMPs, and the OIG's interpretation of them, impede clinical integration comes from a recent court decision. Finding that the Centers for Medicare & Medicaid Services (CMS) lacked the authority to waive the CMP, the court forced CMS to terminate a demonstration project that had been designed specifically to improve the efficiency of surgical services.

What's the Solution?

The CMP law should be amended to make clear it applies only to the reduction or withholding of *medically necessary* services.

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THE ANTI-KICKBACK LAW

What is the Law and Why is it a Barrier?

The anti-kickback law's main purpose is to protect patients and federal health programs from fraud and abuse. The law states that anyone who knowingly and willfully receives or pays anything of value to influence the referral of federal health program business, including Medicare and Medicaid, can be held accountable for a felony. Today, the law has been stretched to cover any financial relationship between hospitals and doctors.

If, as part of a clinical integration program, a hospital rewards a doctor for following evidence-based clinical protocols, the reward could be construed as violating the anti-kickback law. That is because, technically, such a reward could influence a doctor's order for treatment or services. The law carries both civil and criminal penalties and can result in both the hospital and the doctor being barred from Medicare, Medicaid and other federal programs … effectively shutting down the hospital and ending the doctor's career.

The Department of Health and Human Services' Office of Inspector General can protect good medical practices by issuing an advisory opinion. However, advisory opinions are strictly limited to the facts in the letter delivering the opinion, and to the person making the official request for that opinion. They do not protect other clinical integration programs that want to engage in the *very same activity.*

And Congress, recognizing that the anti-kickback statute sometimes thwarts good medical practices, has periodically created "safe harbors" to protect those practices. However, there is no safe harbor for clinical integration programs that reward physicians for improving quality.

What's the Solution?

Congress should create a safe harbor for clinical integration programs. The safe harbor should allow all types of hospitals to participate, establish core requirements to ensure the program's protection from anti-kickback charges, and allow flexibility in meeting those requirements so the programs can achieve their health care goals.

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Getting More *Reform* from Health Reform

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THE IRS

How is the IRS a Barrier to Clinical Integration?

The majority of the nation's hospitals, as not-for-profit organizations, are exempt from federal income taxes. To maintain that not-for-profit status, these hospitals must abide by certain restrictions in the Internal Revenue Code, including one that addresses the payments they provide to physicians, nearly all of whom are not tax-exempt. The rules in question prevent a tax-exempt institution's assets from being used to benefit any private individual, including physicians.

The difficulty arises because not every payment from a tax-exempt hospital to a tax-paying doctor violates the tax code and Internal Revenue Service (IRS) rules. But, until the IRS issues guidance on the subject, tax-exempt hospitals have no assurance about how the IRS will rule in a particular situation, including on payments as part of a clinical integration program. Since the IRS has the power to revoke a hospital's tax exemption or impose large penalties, known as intermediate sanctions, uncertainty about how the IRS will rule can be a significant deterrent to clinical integration.

For example: To facilitate the flow of critical patient information – one of the administration's highest priorities – the Department of Health and Human Services (HHS) recently changed its rules to allow hospitals to share software and Internet connectivity services with doctors. However, it took months of discussion before the IRS provided concrete assurance to tax-exempt hospitals that providing certain financial assistance to help doctors purchase software and connectivity services, which was clearly allowed under HHS rules, would not violate IRS rules.

What's the Solution?

The IRS should issue an Advisory Information Letter or a Revenue Ruling with guidance on payments from a tax-exempt hospital to physicians in clinical integration programs, ensuring that the payments do not violate private-benefit and inurement rules. A Revenue Ruling would have greater impact, because it would provide explicit examples of how the IRS would apply its rules to specific clinical integration arrangements.

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physicians. That staff would be charged with monitoring and providing care both within the hospital and outside the hospital. The article also emphasizes the importance of clinicians in an ACO model, and assesses the hurdles ACOs will have to overcome to comply with antitrust and anti-kickback statutes.
http://www.pepperlaw.com/publications_update.aspx?ArticleKey=1757

15. Deloitte. (2010) *Accountable Care Organizations: A New Model for Sustainable Innovation.*

Summary: The article outlines the promise of the ACO model for improving care delivery, summarizing the structural guidelines of ACOs included in recent health reform legislation and discussing emerging ACO pilots in Massachusetts, Vermont and Colorado. The article argues that the degree of integration within current physician models may be a predictor of early success in creating an ACO. The authors assert that successful ACOs will be defined by strong leadership, governance and operational clinical management capabilities, and outlines the challenges of physician buy-in, consumer response, the structure of payments and managing risk before concluding that ACOs will need to carefully structure provider relationships, accept that results may be slow in materializing and commit themselves to continual improvement as clinical conditions change over time.
http://www.deloitte.com/view/en_US/us/Industries/US-federal-government/center-for-health-solutions/research/bc087956da618210VgnVCM100000ba42f00aRCRD.htm

16. Hastings, D.A. (2009) Accountable care organizations and bundled payments in Health Reform. *Health Law Reporter.*

Summary: The author surveys the landscape of proposed health reform legislation, and notes several legal challenges to ACO development, including the revision of contracts between providers participating in ACOs, compliance with anti-kickback and antitrust statutes, new compliance responsibilities related to adherence to ACO regulations and public reporting, the increased responsibilities of leadership and board management and the integration of bundled payments with ACOs. The article concludes that ACOs and bundled payments both show promise as drivers of health care quality improvement.
http://www.ebglaw.com/files/37716_BNA%20Article%20-%20Accountable%20Care%20Organizations%20and%20Bundled%20Payments%20in%20Health%20Reform.pdf

17. Bass, Berry, and Sims (2010) *The ABCs of ACOs.*

Summary: The article analyzes the legal requirements and hurdles providers will face as they prepare for ACO implementation. Specifically, the article explores ACO compliance with the Anti-Kickback Statute, the Stark Law, antitrust laws and the Civil Monetary Penalty Law, noting that while health care reform legislation did not create safe harbors or exceptions to these statutes in connection to the development of ACOs, the Secretary of HHS has been authorized to waive requirements of these statutes as necessary.
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