

Guidance for Clinical Integration

(Updated) Working Paper

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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 or 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.

GUIDANCE FOR CLINICAL INTEGRATION

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Hogan Lovells for The American Hospital Association

Thomas B. Leary
Robert F. Leibenluft
555 13th Street, NW
Washington, DC 20004

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AMERICAN HOSPITAL ASSOCIATION: MOVING FORWARD ON CLINICAL INTEGRATION GUIDANCE¹

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 processes²⁷ 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 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 integration⁶⁵ 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.

¹ The authors wish to thank Lawrence P. Casalino, M.D., Ph.D, for his very helpful assistance on the initial version of this paper, and to Sharis A. Pozen and Tracy E. Weir who co-authored the initial version.

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.”).

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- 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.