Accountable Care Organizations: Implications for Antitrust Policy

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Introduction

This analysis examines accountable care organizations (ACOs) and assesses their implications for antitrust policy. Consideration of the antitrust implications of ACOs is timely. Both the House and Senate health reform measures contemplate the creation of ACOs as a new class of Medicare provider while providing parallel legal authority under Medicaid. It is also possible that using existing law, the Obama administration might launch ACOs on a pilot demonstration basis.[1]

We begin with a brief overview of the ACO concept and describe legislative proposals to establish ACOs as a formal Medicare and Medicaid provider class subject to special payment rules. We then examine antitrust policy as it relates to clinical and financial integration in health care and consider how antitrust principles might facilitate the formation and operation of ACOs.

Background: ACOs in a Policy Context

Most observers agree that the fractured and fragmented state of American health care is both a cause of poor quality and inefficient care as well as a barrier to improvement. For almost 90 years, advocates of system reform called for greater clinical and financial integration. Early pioneering efforts by both health care providers and group health purchasers to stimulate the growth of prepaid group practice produced enduring examples of system integration such as the Group Health Cooperative and Kaiser Permanente.[2]

But while these notable examples have survived into the modern era, they tend to be the exception rather than the rule, as powerful medical and hospital interests have utilized a range of strategies including attempted group boycotts,[3] passage of anti- "corporate practice of medicine" laws, and outright control over public and private insurance payment policies that would continue to reward financial and organizational autonomy and control.[4] Many of these strategies rested on the assertion that system integration inevitably will place industrial forces in between physicians and their patients, thereby fundamentally damaging this relationship.

As a result, medical care has remained remarkably fragmented, even in the face of mounting evidence regarding the adverse impact of practice isolation on health care quality, patient safety, and cost. Despite passage of the Health Maintenance Organization Act of 1973, whose purpose was to incentivize integration, along with the managed care movement of the 1990s, much of the health

care system continues to operate in isolation,[5] burdened by uncontrolled volume, lack of treatment integration, inability to generate and report on the processes and outcomes of care, and a lack of coordination between medical treatment on the one hand and public health, educational, and social interventions on the other. Although considerable literature documents the quality and efficiency effects of clinical integration,[6] two-thirds of all physicians continue to practice in groups of fifty or fewer, and one-third work either solo or in a practice of two.[7]

The most recent health reform debated has once again raised these same issues. This heightened focus on integration has been spurred on by the 2009 enactment of the Health Information Technology for Economic and Clinical Health Act (HITECH),[8] whose purpose is to achieve widespread adoption and meaningful use of the type of information technology deemed integral to better care integration.

Unlike HMOs or managed care, this latest round of reform is focused on achieving a bottoms-up change in health care practice, rather than a top down integration of practice arrangements into hybrid entities that insure what they furnish. This effort at change appears to be more directly focused on the organization and structure of health care delivery itself, regardless of whether health care systems, once transformed, ultimately become vertically integrated into insured or administered financial arrangements.

In keeping with this search for yet another new pathway toward reform, numerous experts have developed the concept of an "accountable care organization (ACO)"[9] and have called for the incentivization of these new entities through changes in Medicare payment policies aimed at recognizing and financially rewarding this new type of provider class. Of course, through licensure powers, states could undertake a similar effort to spur the creation of integrated care entities, but the advantage of embedding this type of organizational creature in Medicare and Medicaid is the ability to align operational and payment reforms while stimulating similar actions on the part of private payers. The creation of ACOs as a matter of Medicare policy also could have the advantage of transforming the Centers for Medicare and Medicaid Services (CMS) into an active purchaser of integrated health care rather than a simple claims payer under Medicare Parts A and B or certifier of Medicare Advantage (MA) organizations, whose quality and cost limitations have attracted considerable public attention in recent years.[10]

Reflecting these recommendations, the Congressionally-established Medicare Payment Advisory Commission (MedPAC), in its 2009 *Report to Congress,*[11] recommended the legislative establishment of a new provider class consisting of clinically and financially integrated health care entities with which CMS would directly contract for care rather than depending on system reform through MA intermediaries. MedPAC defined an ACO[12] as a group of physicians (possibly including a hospital) that assumes responsibility for annual Medicare spending for a defined patient population. MedPAC noted that ACOs could be compensated for patient care through various payment mechanisms. One model might be a case-based payment mechanism that, much like the Medicare PPS system for hospitals, bundles procedures into a case-based payment structure that incentivizes greater clinical and financial integration in order to reduce costs and improve quality.[13] An alternative payment approach in the case of ACOs of sufficient size and economic strength might be a capitation payment for a fixed group of patients, which would entail a degree of financial risk on the part of the ACO. Whether through bundled case payments or capitation, ACOs thus would assume more robust responsibility for comprehensive health care. In combination with meaningful use of health

information technology, recognition and use of ACOs presumably could yield improvements in quality and efficiency.

Rejecting the mandatory use of ACOs, the House and Senate bills take incremental steps to pilot ACO development and operation, encouraging their establishment and operation but not requiring it as a condition of participation in public insurance programs. The House[14] directs the Secretary of Health and Human Services to undertake a Medicare ACO pilot program that can be scaled up over time, while authorizing a similar scalable demonstration under Medicaid. The Senate [15] authorizes the use of ACOs in the context of a new Medicare shared savings program whose development is mandatory on the Secretary.[16] (The Senate measure also expressly authorizes the establishment of a pediatric ACO Medicaid demonstration).

Whether the focus is directly on savings (as in the Senate bill) or on the model itself (as in the House), the provisions in both bills aim for clinical and financial integration. Both envision the development of new types of practice arrangements that will interact directly with CMS rather than through an insurer-intermediary such as a Medicare Advantage plan, thereby modernizing CMS purchasing practices as well through expansion of direct, value-based purchasing activities that use incentives to change behavior.

Table 1 compares the elements of the House and Senate measures. There are modest differences; for example, the Senate measure does not specifically call for reporting results to a best practices network, nor does the Senate bill expressly call for the testing of specific payment models. But the two measures strongly track each other, emphasizing the creation of a legal structure that would receive payments and make compensation, take on responsibility for care, operate through an integrated provider network, have a demonstrable commitment to quality improvement and performance reporting, and use health information technology.

Table 1.
House and Senate Legislative Proposals: Accountable Care Organizations
(December, 2009)

Required elements for ACO certification	Affordable Health Care for America Act H.R. 3962(House)	Patient Protection and Affordable Care Act H.R. 3590 (Senate)
Accountability for a specific patient population in terms of quality, cost and overall care	√	√
Specific coordination of items and services delivered throughout the continuum of care	√	√
Investment in infrastructure and the re-design of care processes	√	√

Table 1. House and Senate Legislative Proposals: Accountable Care Organizations (December, 2009)		
Required elements for ACO certification	Affordable Health Care for America Act H.R. 3962(House)	Patient Protection and Affordable Care Act H.R. 3590 (Senate)
A legal structure able to receive and distribute payments	√	√
Sufficient number of primary care physicians	√	√
Individual and aggregate reports on quality measurers specified by HHS Secretary in relation to meeting annual quality targets	√	√
Reporting of specific date to HHS Secretary appropriate to monitor and evaluate ACO program	√	√
Contributions to a best-practices network or website to share strategies on quality improvement, care coordination and efficiency mechanisms	√	X
Utilization of patient-centered processes of care including planning and monitoring of ongoing care management plan	√	√
Rewards physician practices and organizational models that deliver high-quality and efficient care	√	√
Testing of specific incentive payment models (i.e. the performance target and partial capitation models)	√	X

Table 1. House and Senate Legislative Proposals: Accountable Care Organizations (December, 2009)		
Required elements for ACO certification	Affordable Health Care for America Act H.R. 3962(House)	Patient Protection and Affordable Care Act H.R. 3590 (Senate)
Utilization of a Shared Savings incentive payment model	√	√
A leadership and management structure that includes clinical and administrative systems	√	√

Central to both measures is the use of payment mechanisms that are structured to promote efficiency, curb excess volume, and spur quality. As noted, such mechanisms might utilize a per-capita payment method for a defined population or, alternatively, an incentive-based fee-for-service arrangement that combines traditional procedure-based payments with performance bonuses targeted at achieving desired changes in volume and quality.

In fact, the ACO model aligns with longstanding antitrust policies, the aim of which has been to not stand in the way of innovative and adequate health care financial and clinical integration arrangements. These policies, as well as the enforcement agencies' experiences in applying them to health care groups, offer important insights into issues in ACO development. These antitrust policies also suggest important avenues for coordination between CMS and the enforcement agencies to the extent that the model proceeds forward.

Antitrust Principles and Clinical and Financial Integration in Health Care

Achieving greater clinical and financial integration in health care has been a central aim of U.S. antitrust policy for nearly four decades. In *Arizona v. Maricopa County Medical Society,*[17] the United States Supreme Court held that efforts by non-integrated medical care associations to set fees charged to insurers constituted a *per se* restraint of trade in violation of Section 1 of the Sherman Antitrust Act, against which there could be no defense of quality or efficiency. The *Maricopa* decision was strikingly direct: in order to avoid *per se* liability, physician arrangements involving joint negotiations with health plans would need to be financially integrated, "analogous to partnerships or other joint arrangements in which persons who would otherwise be competitors pool their capital and share risks of loss as well as the opportunities for profit."[18]

In 1994, in part to clarify the types of health care organizations that would be considered permissible in the wake of *Maricopa*, the Department of Justice and the Federal Trade Commission (the "agencies") issued *Statements of Antitrust Enforcement Policy in Health Care* ("*Statements*").[19] Following the central holding in the *Maricopa* decision, the *Statements* created an express "safety zone" for joint activities by clinical provider entities that had achieved financial integration and that were unlikely to have market power; specifically, Statement 8[20] recognizes "substantial" financial risk as a "reliable indicator of sufficient integration" so as to render reasonably necessary joint contracting conduct

among competitors in order to achieve "significant efficiencies."[21] In other words, if the agencies concluded that sufficient financial risk-sharing was present in a particular provider arrangement, certain activities and behaviors that otherwise would violate federal antitrust law as per se illegal – including the competing providers' joint negotiation of price with payers such as health insurers – would be evaluated under the rule of reason and would not be challenged by the agencies if they lacked market power or did not result in anticompetitive effects. Under a rule of reason analysis, innovative provider arrangements would have the chance to justify their actions by demonstrating the pro-competitive effects of the agreement as well as any proof that the joint negotiations of price were ancillary to the creation of certain efficiencies. A per se judgment, by contrast, means that the activities in question have been conclusively presumed to restrain competition unreasonably even without a study of the market in which they occurred or an analysis of their actual effect on competition.

Provider arrangements that fall short of financial integration do not enjoy protection under the safety zone.[22] In its original issuance of Statement 8, the FTC made clear that the Statement 8 antitrust safety-zones were available only for financially integrated arrangements, because by definition financial integration is likely to involve substantial incentives for efficiencies.[23] However, after much criticism of the notion that, in *Maricopa's* wake, only financial integration could save a physician group from *per se* illegality, the agencies revised and re-issued Statement 8 in 1996. A new and expanded Statement 8 identified *clinical* integration as an additional means for physician groups to avoid antitrust liability for joint negotiation of fees. Clinical integration was a "new and controversial"[24] type of provider joint venture that, even in the absence of significant financial risk, could be justified under a rule of reason analysis. Revised Statement 8 explains that where physician clinical integration is likely to produce significant efficiencies, the FTC will employ a rule of reason analysis – but not an outright safety zone – to review agreements on price that are reasonably necessary to accomplish the venture's efficiencies.[25] The *Statements* offered an example of this type of joint venture: an Independent Practice Association (IPA) established with a paramount goal of clinical efficiency, and where the ability to negotiate price agreements with insurers was necessary for the venture to achieve its legitimate goals. Thus, improving quality and efficiency as a primary purpose of the business undertaking was framed as key to the analysis.

Revised Statement 8 illuminates the agencies' position on what constitutes adequate clinical integration such as to allow collective physician bargaining even in the absence of significant financial risk. The agencies stated that clinical integration typically will involve an "active and ongoing program to evaluate and modify practice patterns by the group's physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality."[26] It is important to note that the agencies did not suggest that the above formulation was the only way to establish clinical integration, but rather one method they had recognized to date; indeed since the issuance of revised Statement 8 those arrangements that have been favorably approved are along those lines, but the agencies left enough flexibility for other acceptable arrangements. Revised Statement 8 offers several examples of indicia of quality and efficiency improvement that in turn would justify joint contracting conduct even in the absence of financial risk-sharing. In essence, the revised Statement recognizes conduct as a single integrated unit as central to viability of the model, even where full financial integration may not be present.[27]

The indicia of interdependence and cooperation identified by the agencies encompassed multiple dimensions including: "systems to establish goals relating to quality and appropriate utilization of services;" regular evaluation of "both individual participants' and a network's aggregate performance

with respect to those goals;" control over practice, as evidenced by the ability to "modify individual participants' actual practices where necessary based on those evaluations;" development of practice standards and protocols "to govern treatment and utilization of services;" use of information systems to gather aggregate and individual data on cost and quality; a dimension of financial risk in the sense of a "significant investment of capital to purchase such systems;" the investment of human resources in collective quality improvement; the upward reporting within the provider arrangement of "detailed reports on the cost and quality of services provided, and on the network's success in meeting its goals;" and a medical director and staff capable of conducting clinical quality improvement and performance reporting activities as well as rate negotiations.[28]

Despite this notable expansion of the *Statements,* until recently the clinical integration doctrine appears to have had only limited impact on the way in which physicians practice; indeed, experts point out that the number of joint ventures actually has declined.[29] Professor Lawrence Casalino, who has conducted extensive research into physician practice behavior (and who also has written on ACOs) identifies a series of factors that in his view have contributed to the low rate of clinical integration. The first is skepticism on the part of practice groups either that their price-fixing contracts will not be flagged or that, if examined, will meet the *Statements'* messenger-model test,[30] which does not require clinical integration. The second is a concern that the investments necessary to achieve clinical integration across independent practices simply is too great to justify the effort; that the financial rewards are too low; that the willingness of payers to negotiate contracts that lack financial risk is too limited; and that uncertainty over the level of integration that must be achieved simply is too high. Moreover, even if an arrangement is clinically integrated, it can still be condemned under the rule of reason if it has market power. And the FTC is wary of arrangements that are exclusive. Thus, providers must realize that even if they invest substantially in a truly clinically-integrated operation, if payers do not perceive that they offer value, they cannot be forced to deal with them on a collective basis – they can contract around them in one way or another. Thus, providers have realized (or they should) that clinical integration is not a way just to get higher fees; rather, providers need to offer value and there is a risk that they create something that no one wants to buy.

Finally, Professor Casalino points out that the problem may lie in physicians' own sense of the health care business: in spite of problems, the high volume of care tolerated by the system means that independence is sufficiently lucrative to offset the effort and risks that accompany clinical integration. Even if no direct financial risk is involved, clinical integration (as recognized by the antitrust agencies), requires sufficient human and financial investment and accompanying loss of independence over practice style to limit the appetite for moving forward.

Commentators also have noted that even where interest is high, the agencies have failed to provide sufficient, broad guidance as to what clinical integration actually entails. Additionally, a group of nine senators recently sent a letter to the agencies urging them to develop more guidance on adequate clinical integration for physicians, hospitals, and other providers.[31] Without proper guidance and assurance from antitrust enforcers, providers are hesitant to attempt clinical integration arrangements for fear of antitrust sanctions. Indeed, one legal expert in health care transactions has called for the establishment of a legislative rebuttable presumption that would incentivize integration by presumptively recognizing the legality of health care arrangements that incorporate indicia of clinical integration,[32] thereby shifting the burden of proof to the enforcement agencies to prove inadequate clinical integration.

FTC Advisory Opinions and Judicial Rulings Regarding Clinical Integration

The FTC has responded to this need for certainty through individual cases and staff advisory opinions rather than through a further elaboration on the subject of clinical integration in the abstract. These agency opinions in turn are helpful in aiding understanding regarding what antitrust enforcers seek when they look for evidence of clinical integration.

Arrangements that have Received FTC Approval

In re Greater Rochester IPA ("GRIPA") (2007) [33]

GRIPA offers an example of a clinically integrated physician arrangement that successfully met the FTC's standard as set forth in the revised 1996 *Statements*. GRIPA positioned its venture as one offering a new health care product that would combine clinical practice with an integrated clinical improvement program designed to improve the quality of care and create efficiencies in the practice of medicine. GRIPA claimed that this new product would be "intertwined" with its proposed joint contracting practices with payers (health insurance companies) on behalf of its 500 independent and hospital-affiliated primary care physicians and specialists in practice across 40 separate areas. The FTC agreed that collective bargaining was reasonably necessary to achieve the program's likely efficiencies.[34]

According to the FTC, GRIPA possessed certain key indicia of clinical integration: (1) a seamless, collaborative network of primary and specialty care physicians who agree to refer patients to one another for care; (2) facilitation of collaboration among GRIPA's physicians through benchmarks, protocols, and performance and compliance monitoring; (3) the use of a web-based, electronic information sharing system that would permit GRIPA physicians to share clinical information related to their common patients, order prescriptions and lab tests, and gain system-wide access to patient information, including information held in hospitals throughout the community; (4) the expansion of care management services to additional long term and chronic health conditions; (5) measurable up-front financial investment, calculated at several thousand dollars per physician as well as ongoing practice costs; and (6) a solid calculation of savings attributable to the expected efficiencies.[35]

Reflecting the revised 1996 Statement 8 requirement that any collective bargaining over price must be reasonably necessary to achieve the stated efficiencies of the proposed clinically integrated arrangement, GRIPA, in the FTC's view, was able to justify its price negotiation activities because the entity (1) created an easily identifiable network of providers and referring physicians; (2) reinforced the internal referral system; (3) ensured the presence of common financial goals among physicians; (4) increased collaboration opportunities; (5) demonstrated its ability to sanction non-performing physicians; (6) showed a major financial investment; (7) significantly reduced administrative costs and burdens; and (8) could achieve its efficiency aims only through real clinical integration.[36]

An important dimension of the review focused on the fact that GRIPA was "non-exclusive," so that there was no impediment to health plans that wished to contract directly with physicians and not deal with GRIPA at all. The GRIPA opinion also marked the first time FTC explicitly acknowledged

that a clinical integration program could legitimately result in higher fee schedules if the program reduced utilization, improved quality, and ultimately delivered greater "value."

In re MedSouth (2002 and 2007)

In re MedSouth offers an important example of a proposed joint contracting activity that was initially approved and then evaluated after it was operational. In 2002, MedSouth received FTC approval[37] after proposing to create a new arrangement that combined non-exclusive joint contracting with a web-based data system that allowed participating physicians to share clinical information about their patients. The MedSouth joint venture also reflected several recognized indicia of clinical integration: (1) a requirement that its physicians comply with agreed-upon protocols; (2) active monitoring of compliance; (3) a system to compare physician performance to established network benchmarks and institute corrective action programs for deficient performance; and (4) the ability to expel from the network those physicians who could not or would not comply with the program's requirements.[38]

In its 2002 approval of the MedSouth program, the FTC noted two primary reasons why joint contracting appeared to be reasonably necessary to achieve the program's stated efficiency goals. First, the FTC determined that the ultimate success of the new arrangement could not be attained if each physician separately contracted with payers, because there would be no guarantee of full participation by all the program's members. Second, the FTC found that the joint contracting enabled the program to allocate returns to individual physicians thus providing monetary incentives for the physicians to invest the required time and effort in the program.[39] The FTC stated in its 2002 advisory opinion that the agency would not seek enforcement action against MedSouth, but that the agency would revisit MedSouth's effect on competition and its success in achieving efficiencies at a later date.

In keeping its promise, a subsequent 2007 FTC re-evaluation of the MedSouth program led to a new advisory letter noting a significant decline in the number of participating physicians, which in turn limited the benefit of a comprehensive multi-specialty network; the absence of appropriate health information privacy and security safeguards; the absence of a sufficiently strong mechanism for monitoring and enforcing practice standards; and the lack of evidence that payers were getting value for their investment, that is, were deriving sufficient benefits of clinical integration to justify the contract price. Nonetheless, the FTC continued its approval of joint non-risk contracting as necessary to achieve clinical efficiency. This is significant because the ability to maintain the joint contracting aspect of the clinical integration arrangement is critical both in terms of achieving the claimed efficiencies as well as providing the physicians greater bargaining power with payers.

In re TriState Health Partners, Inc., April 13, 2009 ("TriState")[40]

In re Tristate offers a particularly noteworthy example of an FTC staff approval of a clinical integration model, because of the breadth of the FTC reasoning regarding the potential of a model to achieve efficiencies sufficient to justify joint contracting without financial risk. TriState is a physician-hospital organization that includes a hospital and 212 physicians, both primary care and specialists. Its proposed program purports to "offer payers a network of primary care and specialist physicians whose services will be integrated through a formal and stringent medical management program that includes protocol development and implementation, performance reporting, procedures for corrective action when necessary, and aggressive management of high-cost, high-risk

patients."[41] Physicians seeking to participate in the program must become members of TriState through an application, credentialing process, and a $2,500 joining fee. Member physicians must participate in all TriState payer contracts, but may also contract independently with insurers directly.

In order to justify its collective bargaining of price, TriState described several specific aspects of its clinical integration program: (1) compulsory participation in all medical management programs, service on clinical committees, and sharing of best practice ideas and methods; (2) a requirement that physicians refer patients to network providers when medically appropriate; (3) use of a web-based HIT system that can identify high-risk and high-cost patients and can facilitate the exchange of patients' treatment and medical management information; (4) the development of 18 clinical practice guidelines with 30 more under development and the monitoring of adherence to these guidelines; (5) the use of specific software to manage and track "episodes of care" in order to determine where performance improvement will have the greatest quality and financial benefits; (6) the monitoring of physician performance against peer, regional, and national benchmarks; and (7) a program of education, discipline, and expulsion from the program for non-compliant physicians.[42]

In its advisory opinion, the FTC identified several factors to be used when analyzing whether a proposed integration plan is likely to achieve significant efficiencies that justify joint contracting.[43]

- Factor #1: Is the program selective in choosing network physicians who are likely to further the program's efficiency objectives? The FTC noted that while not initially selective (any physician can join), there did exist a number of conditions of participation that would effectively discourage those not fully committed.

- Factor #2: Are the participating physicians investing both monetary and human capital into the program? The FTC determined that while the $2,500 entry fee was too low to "strongly motivate" physicians to work towards the success of the program, the human capital in terms of time and effort did evidence a substantial degree of commitment to the program.

- Factor #3: Will the structural and operational elements of the program foster significantly increased interaction among the participating physicians in the treatment of patients? Here, the FTC noted the emphasis on clinical practice guidelines and evidence-based standards, an in-network referral policy, the use of HIT, the collection and use of performance data, a requirement that all physicians participate in all aspects of the program, and performance feedback mechanisms that carried enforceability consequences.

- Factor #4: Is there adequate information regarding how the program will be evaluated over time? Although this element appeared to be lacking in TriState's program, the FTC recognized the past success of a similar pilot program offered by Tri-State as predictive.

- Factor #5: Does the participation of the hospital create an inherent conflict in terms of the hospital's need to fill beds? The FTC determined under the facts presented, and because of Maryland's unique all-payer hospital rate regulation system, the hospital did not have an incentive to provide excess services. The program's medical management processes, in the opinion of the FTC, were strong enough to overcome any potential conflicts of interest.

TriState is noteworthy in that it received a favorable review notwithstanding relatively small financial investments from its existing physician members, lax initial membership requirements, little detail regarding how it intended to improve physician performance, the absence of financial incentives, and substantial market shares of both the physicians, and the hospital. The TriState opinion was also the first favorable review of a Physician-Hospital Organization clinical integration program, which can be viewed as the probable forerunner to ACOs that form around hospitals.

In its analysis, however, the FTC found that TriState's program was likely to produce its claimed efficiencies. The next stage of the inquiry focused on whether the joint contracting portion of the program was reasonably necessary to achieve these efficiencies. Concluding that the joint contracting was indeed necessary, the Agency identified several important considerations: the link between the program's success and universal participation among physicians in all contracts under the same criteria and protocols; an in-network referral policy reinforced through joint contracting; incentivization of physician participation through a greater number of contracts; the existence of economies of scale; branding through a single entity; and a reduction in administrative overhead.[44]

Arrangements Rejected by the FTC and the Courts

In re Suburban Health Organization, Inc. ("SHO")[45]

In re Suburban Health Organization offers an example of a clinical integration arrangement that did not pass muster with the FTC. SHO was a proposed program of partial integration among several hospitals and their employed primary care physicians. Under the joint contracting element, SHO negotiated the rates of primary care physician services on behalf of its members, and such negotiations were the exclusive means through which payers could gain access to those services. SHO's proposed clinical integration consisted of: (1) medical management activities that included patient monitoring and adoption of practice guidelines and protocols for preventative care as well as four other specific conditions; (2) quality management programs designed to measure physician compliance and identify opportunities for improvement using web-based technology; (3) the distribution of educational materials to physicians and staff; and (4) an incentive program intended to encourage physician compliance with program requirements through a bonus equal to five percent of their compensation for meeting quality management targets.

The FTC staff opinion rejected SHO's clinical integration program, stating that joint contracting was not reasonably necessary to achieve program efficiencies. The deficiencies in the arrangement that were identified by the FTC are noteworthy. First, the FTC could find no evidence to explain why several hospitals needed to be involved in the integration and concluded that a hospital could reap the same benefits by implementing the program independently. Second, the model showed too much reliance on hospitals to track, reward, and discipline the physicians for non-compliance, and there was no mechanism for disciplining hospitals for their failure to monitor performance. Third, the FTC found little evidence of interdependence among physicians in the provision of coordinated care. Fourth, the FTC found inclusion of too few diseases and medical diagnoses. Fifth, the lack of specialists in the program limited the benefits in terms of treatment. Finally, the FTC found implausible SHO's claim that the program would track the effectiveness of referrals to nonparticipating specialists.

SHO's lack of adequate clinical integration led the FTC to determine that the joint contracting by the physicians was indeed problematic under antitrust law because it did not appear necessary to achieve any efficiencies in the provision of care. Specifically, the FTC stated "it is not evident, and SHO provides no explanation, why agreement on the entire schedule of fees to be charged for all medical services performed by the employed primary care physicians in SHO is necessary to implement a program that only addresses treatment of a very limited subset of medical conditions treated by those physicians."[46] Because there was such limited primary/specialty interdependence, such heavy reliance on a non-enforceable monitoring system, and so little in the way of a mechanism for transforming the provision of care for a broad array of conditions, joint contracting without financial integration could not be justified against the efficiencies to be achieved. An important aspect of the case in the view of Robert Leibenluft, former Assistant Director for Health Care of the Federal Trade Commission's Bureau of Competition, was that the physicians all were employed by their respective hospitals; thus, hospitals could have exercised greater control over practice quality and efficiency from the outset, thereby obviating the need for a broader clinical integration program that would allow joint negotiations across facilities.

North Texas Specialty Physicians v FTC ("North Texas")

A widely watched judicial ruling was *North Texas Specialty Physicians v. FTC,*[47] which flowed from a denial. Both the FTC and the courts rejected this non-risk joint contracting proposal precisely because it lacked sufficiently robust indicia of clinical integration to merit the anti-competitive effects of collective bargaining. In *North Texas,* physicians formed an IPA, which then carried out rate negotiations on behalf of its members. The IPA failed to consult with individual members regarding the prices they would accept, instead simply transmitting to its members the rates that it had agreed to collectively. At the same time, the IPA failed to engage in the types of clinical integration practices that might have justified and indeed necessitated its joint contracting practices.

In affirming a unanimous FTC decision, the Court of Appeals for the Fifth Circuit concluded that the IPA's collective bargaining was not reasonably necessary to achieve any efficiency-enhancing integration and thus constituted illegal price-fixing.[48] Other than shared investment and joint contracting, the IPA lacked the types of transformative elements identified in the *Statements* and in the FTC advisory letters that necessitate joint contracting; indeed, the entity lacked the indicia that would necessitate the type of collective negotiation that the FTC views as essential to enabling clinical integration.[49]

In re Alta Bates[50]

Similarly, in June 2009, the FTC announced a proposed consent order aimed at settling a dispute involving the Alta Bates Medical Group, which stood accused of illegal price fixing in connection with contracts in the San Francisco area. As with *North Texas,* the FTC determined that the 600-member IPA had negotiated collectively for years without following the messenger model requirement of consultation with individual physicians and without adopting the all-important indicia of clinical integration that would justify a collective approach to the negotiation process rather than the use of individual consultation procedures.[51]

Table 2, below, presents the key indicia of clinical integration – apart from evidence of financial integration through the acceptance of significant financial risk – identified by the FTC in its advisory

opinion letters. As in the *Statements*, a favorable finding fundamentally rests on a basic commitment to measurable human and financial investments in quality and efficiency improvements as measured by evidence of collective financial and operational practice, performance accountability, a strong commitment to changing practice for patients across a wide array of health conditions, performance measurement, the use of health information broadly, and a greater commitment to information transparency.

Taken together, the decisions rest on a crucial finding by the enforcement agencies: sufficient evidence of *collective and interdependent* efforts to create the potential for significant efficiencies – such as higher quality, better use of cost effective care, and more value – that go beyond what likely would have been achieved independently and that justify the anticompetitive restraints (including joint negotiation with payers) that are reasonably necessary to achieve those efficiencies. Table 2 shows the indicia and characteristics that are common to the cases and that help guide the agencies in their review of conduct.

Table 2.
Indicia of Clinical Integration that Justify
Joint Contracting in the Absence of Financial Integration

Aspect of clinical integration product	**GRIPA** (approved)	**MedSouth** (approved)	**SHO** (rejected)	**TriState** (approved)
Adequate number of diagnoses and diseases covered by clinical integration	√	√	X	√
Agreement by physicians to refer in-network	√	√	X	√
Both specialists and primary care physicians in network	√	√	X	√
Financial investment by physicians	√	√	X	√
Human resource investment by physicians	√	√	X	√
Technology that enables multiple physicians to gain access to and share patient information	√	√	X	√

Aspect of clinical integration product	**GRIPA** (approved)	**MedSouth** (approved)	**SHO** (rejected)	**TriState** (approved)
Streamlined recordkeeping and operations, including the use of electronic lab orders & prescriptions	√	√	X	√
Enforceable performance standards and a demonstrated capacity to enforce the standards through adequate staffing	√	√	X	√
A non-exclusive arrangement	√	√	X	√
Joint contracting that aligns with a broad array of conditions and diagnoses subject to clinical integration performance measurement and improvement	√	√	X	√
Upward reporting of results, in terms of both aggregate and individual physician Performance	√	√	X	√

Source: modification of table developed by Simon et al. in *Clinical Integration: a Guide to Working with the Federal Trade Commission to Enhance Care Through Pro-Patient, Pro-Innovation, Pro-Efficiency Provider Networks*, Health Lawyers Weekly, The American Health Lawyers Association, January 30, 2009 Vol. VII Issue 4.

Interaction of Accountable Care Organization and Antitrust Enforcement Policy

A comparison of ACO characteristics and those used by the FTC to determine whether the goal of clinical integration has been met to a degree sufficient to justify collective financial negotiation shows a high degree of concordance. This degree of concordance would be even more so in ACO models that employ both clinical integration and financing arrangements that rely on population-based capitation and use of a salary-plus-performance-bonus payment system. In this case, an ACO appears to attain the level of financial integration expressly recognized for purposes of safety-zone treatment.

At their heart, both the ACO model and the FTC criteria demand the existence of a structure dedicated to quality and efficiency and possessing both the mission and the authority to impose practice, reporting, and compensation standards (including penalties and rewards) across a group of physicians on behalf of the patient population. Particular emphasis in both models is placed on the formation of large practice groups that take responsibility for a group of patients and that adopt an approach to practice that achieves integration as measured by adherence to quality protocols and performance measurement, the exchange of information, and the reporting of outcomes. In both models, the group ultimately comes to operate as one, facing the risks and enjoying the rewards (whether in the form of profit sharing or performance bonuses) of efficiency and quality. Furthermore, in both cases, the organizational model can exist without regard to whether the model assumes significant financial risk, although even where only clinical integration is present, the agencies will look for evidence that the participants recognize the entity as a common enterprise, as revealed through the investment of financial and sweat equity.

The parallels between ACOs and the FTC/DOJ antitrust guidelines and opinions suggest the value of further coordination between HHS and DOJ/FTC in the event that the ACO provisions in the health reform legislation become law. The central question becomes whether, and under what circumstances, entities that are certified as ACOs would be treated as falling within the parameters established by the FTC and DOJ. Where an ACO achieves financial as well as clinical integration through use of capitation or other global payment mechanisms that underlie the acceptance of financial risk, one might anticipate that the entity also would receive a Statement 8 safety-zone assuming that other considerations such as market share are satisfied.

The additional question is how to treat ACOs that receive Medicare certification but that are not considered financially integrated within the meaning of the Statements because of the absence of a capitation or global payment system that supports clinical integration activities. In this case, one option might be the development of a presumptive approval standard; that is, a less rigorous review than what might be needed under a "rule of reason" test and that (assuming market size considerations are satisfied) treats the CMS certification as evidence of integration at a level sufficient to meet the expectations of the enforcement agencies.

The benefit of this type of presumptive approval would be an added inducement in ACO formation, since the entity, once formed, could conduct business in other payer markets and thus grow its presence in such market. Once fully certified and operating as a fully clinically and financially integrated entity, an ACO presumably should be able to negotiate with private payers from this position of clinical integration, although issues of market power will still bear careful scrutiny. This additional level of coordination between CMS and the enforcement agencies would mean that as CMS moves to use its Medicare certification and payment powers to influence the rate of clinical and financial integration, entities coming under the CMS umbrella would be further positioned to negotiate similar terms with other payers in the employer market and the new Exchange, and in expanded Medicaid markets that are the anticipated product of national health reform. This added market reach would, in turn, spur the reach of health information technology, integrated clinical practice, and efficiency strategies further into the patient population.

What is clear is that there is the potential for policy synergy between emerging federal ACO policy on the one hand and antitrust policy on the other. How the federal government coordinates these policy levers to produce a greater push toward integration, technology-enabled health care, quality

improvement, and the production of comprehensive health information, should be counted as one of the most closely watched follow-on activities of national health reform.

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[1] Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, § 646 (2003).

[2] Paul Starr, *The Social Transformation of American Medicine* (Basic Books, 1982) pp. 261-267.

[3] *American Medical Association v. United States*, 317 *U.S.* 519 (1943).

[4] Rand Rosenblatt, Sylvia Law and Sara Rosenbaum, *Law and the American Health Care System* (Foundation Press, 1997) Chapter 2 (H).

[5] A particularly vivid portrayal of this landscape and its consequences in some health care markets can be seen in a seminal 2009 article by Dr. Atul Gawande, "The Cost Conundrum: What a Texas Town Can Teach Us About Health Care," *New Yorker* June 1, 2009 *http://www.newyorker.com/reporting/2009/06/01/090601fa_fact_gawande* (Accessed February 25, 2010).

[6] Elliott S. Fisher et al., *Achieving Health care Reform – How Physicians Can Help*, 360 New Eng. J. Med. 24, 2495-97 (2009); Elliott S. Fisher & John E. Wennberg, *Health Care Quality, Geographic Variations, and the Challenge of Supply-Sensitive Care*, 46 Perspectives in Biology & Med. 1 (2003); Francois de Brantes et al., *Building a Bridge from Fragmentation to Accountability – The Prometheus Payment Model*, 361 New Eng. J. Med. 11, 1033-36 (2009); Alice G. Gosfield & James L. Reinertsen, *Finding Common Cause in Quality: Confronting the Physician Engagement Challenge*, 34 Physician Executive J. 2, 26 (2008); James C. Robinson & Jill M. Yegian, *Medical Management After Managed Care*, W4 Health Aff. 269, 269-80 (2004), http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.269v1; *see generally* Comm. on Quality Health Care in Am., The Inst. of Med., Crossing the Quality Chasm: A New Health System for the 21st Century (Nat'l Acad. Press 2001).

[7] Ellyn Boukus et al., *A Snapshot of U.S. Physicians: Key Findings from the 2008 Health Tracking Study Physician Survey*, Center for Studying Health System Change, Data Bulletin No. 35 (2009) available at http://www.hschange.com/CONTENT/1078/.

[8] Codified at 42 U.S.C. §§ 201 et seq. (Public Health Service Act amendments); 42 U.S.C. §§ 1848 et seq. (Medicare and Medicaid adoption incentives). HITECH was included in The American Recovery and Reinvestment Act of 2009 (ARRA), Public Law 111-5, 111th Cong. 1st sess. (2009), Title XIII Division A and Title IV Division B (authorizing approximately $49 billion in funds to incentivize providers' adoption of health information technology by "meaningful users" in the Medicare and Medicaid programs).

[9] Steve Shortell and Lawrence Casalino, "Health Care Reform Requires Accountable Care Systems," *JAMA* 298:673-676 (July 2, 2008); Elliot Fisher et al., "Fostering Accountable Health Care: Moving Forward in Medicare," *Health Affairs* (web exclusive) March/April 2009; 28(2): w219-w231.

[10] See, e.g., Brian Biles et al., "The Continuing Cost of Privatization: Extra Payments to Medicare Advantage Plans Jump to $11.4 Billion in 2009." The Commonwealth Fund, May 4, 2009; Brian Biles and Jonah Pozen, "Paying Medicare Private Plans By Competitive Bidding: Not The Same As Costs In Regular Medicare." July 2009.

[11] 2009 Report to Congress: Improving Incentives in the Medicare Program http://www.medpac.gov/chapters/Jun09_Ch02.pdf (Accessed February 25, 2010).

[12] David Glass and Jeff Stensland, Accountable Care Organizations (MedPAC, Washington D.C. 2008) http://www.medpac.gov/transcripts/0408_ACO_public_pres.pdf (Accessed February 25, 2010).

[13] The ability to combine a fee-for-service payment methodology with the type of prospective budgeting that is reflected in bundled payments potentially has been enhanced by the development of payment tools such as Prometheus, which allow the use of traditional payment methodologies while still permitting payers to create efficiencies in how the cost of care is budgeted and accounted for. See Francoise de Brantes, Meredith Rosenthal, and Michael Painter, "Building a Bridge from Fragmentation to Accountability: the Prometheus Payment Model," *New Eng. Jour. Medicine* 361:1033-1036 (September 10, 2009) http://content.nejm.org/cgi/content/full/361/11/1033 (Accessed February 25, 2010).

[14] Affordable Health Care for America Act, H.R. 3962 §§ 1301 et seq., 111th Cong. (1st Sess. 2009). Available at http://frwebgate.access.gpo.gov/cgibin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3962eh.txt.pdf.

[15] Patient Protection and Affordable Care Act, H.R. 3590 §§ 3022 et seq., 111th Cong. (1st Sess. 2009). Available at http://democrats.senate.gov/reform/patient-protection-affordable-care-act.pdf.

[16] *Id.*

[17] 457 U.S. 332 (1982).

[18] *Id.* at 356.

[19] *Statements of Antitrust Enforcement Policy in Health Care,* Washington: Federal Trade

Commission and U.S. Department of Justice, 1996, http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm (Accessed February 25, 2010).

[20] *Statements of Antitrust Enforcement Policy in Health Care,* Washington: Federal Trade

Commission and U.S. Department of Justice, 1996, Statement 8. http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm (Accessed February 25, 2010).

[21] Casalino L, "The Federal Trade Commission, Clinical Integration, and the Organization of Physician Practice," *JHPPL* 31:3 (June 2006) 569, 571.

[22] Specifically, for protection under the safety zone, the financially-integrated physician network must also lack market power through a showing that the network encompasses less than 20% of physicians in a market (or 30% if the arrangement is non-exclusive). Networks involving non-physicians, or which are clinically but not financially integrated, or which involve a higher percentage of physicians, may also be legal and avoid per se condemnation, but are not in a safety zone.

[23] Thomas Rosch, Commissioner, Federal Trade Commission, *Clinical Integration in Antitrust: Prospects for the Future*, Remarks to ABA Antitrust Section and the American Health Lawyers Association, September 17, 2007 available at http://www.ftc.gov/speeches/rosch/070917clinic.pdf.

[24] Casalino, supra note 21 at 571.

[25] *Statements of Antitrust Enforcement Policy in Health Care,* Washington: Federal Trade

Commission and U.S. Department of Justice, 1996, Statement 8(B).
http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm (Accessed February 25, 2010).

[26] *Id.*

[27] It should be noted that for multi-provider networks that include more that just physicians, Statement 9 explains that no safety zones are available for joint activities among otherwise competing providers. Statement 9 makes clear that a rule-of-reason analysis will be employed by agency antitrust enforcers to determine whether either sufficient financial or clinical integration exists within the multi-provider network to justify joint activities, such as collective price negotiation. *Statements of Antitrust Enforcement Policy in Health Care,* Washington: Federal Trade Commission and U.S. Department of Justice, 1996, Statement 9.
http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm (Accessed February 25, 2010).

[28] U.S. Department of Justice & Federal Trade Commission, Statements of Antitrust

Enforcement Policy in Health Care (1996), Statement 8 (C)(1)
http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm (Accessed February 25, 2010).

[29] Casalino, supra note 21 at 573.

[30] The messenger model involves the use of an entity that represents the physicians and avoids horizontal price-fixing because the entity does not negotiate with health plans but simply "messengers" fee proposals back-and-forth between individual physicians and payers until individual agreements as to price are reached.

[31] Press Release, "Senators Urge Antitrust Agencies to Issue Guidance on Clinical Integration, Request GAO Conduct Studies of Current Law," *Health Lawyers Weekly*, The American Health Lawyers Association, January 8, 2010 Vol. VIII Issue 1.

[32] Hastings D, "Addressing the Legal Issues in Achieving Quality and Cost Efficiency: The Need for A Rebuttable Presumption," *BNA Health Law Reporter* 18:740 (June 5, 2009).

[33] Federal Trade Commission, In re Greater Rochester Independent Practice Association Advisory Opinion (2007), http://www.ftc.gov/bc/healthcare/industryguide/advisory.htm (Accessed February 25, 2010).

[34] *Id.*

[35] *Id.*

[36] *Id.* See also Simon D. et al., "Clinical Integration: a Guide to Working with the Federal Trade Commission to Enhance Care Through Pro-Patient, Pro-Innovation, Pro-Efficiency Provider Networks," *Health Lawyers Weekly*, The American Health Lawyers Association, January 30, 2009 Vol. VII Issue 4.

[37] Federal Trade Commission, In re MedSouth, Inc. Advisory Opinion (2002 & 2007), http://www.ftc.gov/bc/healthcare/industryguide/advisory.htm (Accessed February 25, 2010).

[38] *Id.*

[39] *Id.*

[40] Federal Trade Commission, In re TriState Health Partners, Inc. Advisory Letter (2009) http://www.ftc.gov/bc/healthcare/industryguide/advisory.htm (Accessed February 25, 2010). See also Johnson C, "Federal Trade Commission Issues New Advisory Opinion Approving Joint Contracting for Clinically Integrated PHO," *Health Lawyers Weekly*, The American Health Lawyers Association, May 22, 2009 Vol. VII Issue 20.

[41] *Id.*

[42] *Id.*

[43] See Johnson C., supra note 40.

[44] *Id.*

[45] Federal Trade Commission, In re Suburban Health Organization, Inc. Advisory Opinion (2006) http://www.ftc.gov/bc/healthcare/industryguide/advisory.htm (Accessed February 25, 2010).

[46] *Id.*

[47] 528 F.3d 346 (5th Cir. 2008).

[48] *Id.*

[49] *Id.*

[50] *In re Alta Bates Medical Group, Inc.* FTC, No. 051 0260, settlement announced June 4, 2009.

[51] *Id.*