Aligning Health Care Market Incentives in an Information Age: The Role of Antitrust Law

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I. Introduction

On May 11, 2009, the Obama Administration announced a new antitrust enforcement policy that promises increased anti-trust scrutiny for many industries, including health care, a reversal of the previous administration's approach, which strongly favored businesses against anti-trust claims. Of particular concern in the health care sector has been the increasing consolidation of insurers, as well as hospital and health system mergers that produce market-dominant health care players impervious

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to price and price collusion. At the same time, certain forms of collaboration among competitors are foundational to advancing overarching health system goals, particularly system-wide improvements in the quality and efficiency of health care within the local geographic markets in which Americans receive most of their care. Altering the way in which physicians, hospitals, and other health care suppliers relate to one another in these markets is essential to improving the quality of care, as numerous commentators have pointed out.

The current health care picture in local markets is one of high interdependence, while at the same time wracked by disjuncture. Although there are various forms of health insurance within a local market (e.g., hundreds of public and private employer-sponsored health benefit plans, Medicare, Medicaid and the State Children’s Health

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9 See Gawande, supra note 8.


Insurance Program\textsuperscript{13}, to a great degree patients often share the same medical and health professionals,\textsuperscript{14} pharmacies and hospitals. Experts suggest that it is the performance of the underlying system of health care professionals, rather than the limitations of any particular insurer, that is associated with key quality measures.\textsuperscript{15} To achieve health care quality improvement, health care providers must not only perform well in terms of their own clinical areas of competency, but also in relation to one another.\textsuperscript{16} Health care providers' ability to collaborate with each other in the common care of patients is essential to the effective treatment of individuals with serious and chronic health conditions (e.g., diabetes with its attendant consequences accompanied by depression), whose effective treatment and management represent the acid test for system quality and efficiency.\textsuperscript{17} Given the prevalence of serious medical conditions among Americans compared to residents of other nations\textsuperscript{18} and the excessive cost of U.S. health care,\textsuperscript{19} improving the quality of health care and decreasing health care costs by integrating health services are foundational goals for the nation.

Despite this, the system remains fractured. Two thirds of all physicians continue to practice in groups of fifty or fewer, and one-third work either solo or in a

\textsuperscript{12} 42 U.S.C. §§ 1396-1396v (2009).
\textsuperscript{13} 42 U.S.C. §§ 1397-1397f (2009).
\textsuperscript{14} See Ellyn Boukus et al., Ctr. for Studying Health System Change, \textit{A Snapshot of U.S. Physicians: Key Findings from the 2008 Health Tracking Study Physician Survey}, Data Bulletin No. 35, 3 (Sept. 2009), http://www.hschange.com/CONTENT/1078/ (noting that Medicaid beneficiaries have decreasing access to physicians because of the rising number of physicians who do not accept Medicaid compared to those who do not accept commercial insurance).
\textsuperscript{15} See Gawande, \textit{supra} note 8 (comparing per patient medical costs between cities and suggesting that insurance limitations are not primary reason for excessive costs).
\textsuperscript{16} See id. (discussing effectiveness and efficiency of collaborative policies of Mayo Clinic compared to other practices).
\textsuperscript{17} See id. \textit{See also} Anne C. Beal et al., \textit{Closing the Divide: How Medical Homes Promote Equity in Health Care}, COMMONWEALTH FUND Vol. 62, June 27, 2007, \textit{available at} http://www.wafp.org/documents/ClosingtheDivide.pdf (citing benefits of health care setting that provides timely, well-organized care, and enhanced access to providers).
\textsuperscript{18} See Kenneth E. Thorpe et al., \textit{Differences In Disease Prevalence As A Source Of The U.S.-European Health Care Spending Gap}, 26 HEALTH AFF., 678, 678-86 (2007) (results of study of disease prevalence in U.S. compared to European countries).
\textsuperscript{19} See Bruce Siegel et al., \textit{Private Gain and Public Pain: Financing American Health Care}, 36 J. LAW, MED. & ETHICS 644, 645-50 (2008) (discussing factors contributing to increasing health care costs). Medicare and Medicaid are the "largest contributor[s] to anticipated long-term growth in federal spending." \textit{See id.} at 645. While the aging population and uninsured are also factors in the increased health care costs in the United States, it is the "confluence of rapid technological advance and intense commercialism in medicine" that is a much larger factor in the cost spike. \textit{Id.}
Health information technology ("HIT") adoption stands at exceedingly low levels, even though such technology, once adopted and in use, has the potential to overcome the siloing of medical care that is the result of a market consisting of countless small and mid-sized purveyors of health care.

It is true that American consumers want the freedom to choose their doctors, their hospitals, their pharmacies, as can be seen by the very low level of member enrollment in staff model HMOs in which patient choice is limited to a tightly controlled network. Even when members of health plans linked to "preferred provider organizations" (the far more popular, loose confederacy of physicians that sell discount health care to plan members) confront providers with full panels and limited choice, they still like the concept of choice, illusory as it may be. Yet at the same time, patients depend, in ways they cannot always appreciate, on provider collaboration and cooperation whether in the form of shared call at hospitals, acceptance of patient referrals, or community-wide response to public health threats. Particularly in times of threat, we all may want to choose our doctors, but we also want our doctors and hospitals to collaborate in ways that advance our collective public health, and in ways that help us when we are sick.

In recent years, two developments have further spurred this ongoing desire for collaboration. One is a veritable deluge of evidence underscoring problems of cost and...
quality both within and among health care markets.\textsuperscript{25} Whether the measure is excessive use of unsafe testing procedures, preventable errors in hospitals, the absence of real-time information to guide complex practice decisions, or something else, stories of quality lapses and outlandish costs abound.\textsuperscript{26} Experts in health care market economics point to greater competition as the best means of reducing the price charged for individual health care items, services and procedures, but at some point it becomes evident that discount pricing alone does not equate to value and efficiency.\textsuperscript{27} Quality, value and efficiency turn on integration where health care is concerned, simply arranging to buy particular services and procedures in bulk volume (e.g., a physician network for 35% off the full retail price) is not enough.\textsuperscript{28}

Producing health care is not like producing widgets: the evidence suggests that improving health care takes extensive and ongoing collaboration among key players in a joint, information-driven, approach that causes those who otherwise might be competitors to come together to confront problems and devise solutions.\textsuperscript{29} Where the health care system operates as a single staff-model or an exclusively contracted integrated delivery arrangement (such as the Veterans Administration or the classic staff model prepaid practice plan, Group Health), a singular and unified approach to quality

\begin{footnotesize}
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\item[28] See Fisher, supra note 8, at 2496.
\item[29] See DEP’T OF HEALTH AND HUM. SERVICES, CONFRONTING THE NEW HEALTH CARE CRISIS: IMPROVING HEALTH CARE QUALITY AND LOWERING COSTS BY FIXING OUR MEDICAL LIABILITY SYSTEM 18-24 (2002), available at http://aspe.hhs.gov/daltcp/reports/lierefm.pdf. This is because collaboration in the medical community results in better, more cost effective solutions to on-going issues. See id.
\end{enumerate}
\end{footnotesize}
and efficiency improvement is possible.\textsuperscript{30} This structural approach to the challenge of health care, however, does not describe the current health care market. As the data on health plan enrollment by type shows, the vast majority of consumers are insured are members of health benefit plans\textsuperscript{31} that offer no organized health care delivery arrangement, that leave consumers free to wander among lists of doctors, therapists, hospitals, pharmacies, and other health care providers that may or may not have anything to do with one another.\textsuperscript{32} Only a few consumers demand more from the health care system, because so many do not know where to begin. As for physicians and hospitals, they make a good deal of income from the system as it stands, lacking any particular incentive to make matters better.\textsuperscript{33} Indeed, in some communities, physicians and hospitals are imbued with every incentive to positively abuse the system itself, not to mention the patients for which they provide care.\textsuperscript{34}

\textsuperscript{30} Id. The President believes this good faith effort to improve the system should be protected and allowed to continue. See id. at 24.


\textsuperscript{32} See id.

\textsuperscript{33} See Gawande, supra note 8 (noting lack of incentive). The Institute of Medicine has reported preventable error deaths among as many as 98,000 hospital patients in a single year, and a seminal study of the quality of health care which analyzed hundreds of quality indicators for thirty acute and chronic conditions as well as use of preventive care, found that patients received appropriate care only 55% of the time. See Kohn, supra note 26, at 1; see also McGlynn et al., The Quality of Health Care Delivered to Adults in the United States, 348 NEW ENG. J. MED. 2635, 2635-45 (2003).

\textsuperscript{34} See Gawande, supra note 8 (discussing abuse). According to the Congressional Budget Office ("CBO"), the bulk of the growth in health care expenditure is a result of the development and diffusion of new medical technologies and therapies, not from demographic shifts or increasing disease prevalence. See Siegel et al., supra note 19, at 648 (concluding technologies main driver behind rising health care cost). Studies suggest that excessive use of costly treatments result in serious lapses in quality. See Peter R. Orszag & Phillip Ellis, The Challenge of Rising Health Care Costs — A View from the Congressional Budget Office, 18 NEW ENG. J. MED. 1793, 1793-95 (2007) (noting lapse); see also McGlynn et al., supra note 33, at 2641-44 (arguing that deficits in care are also associated with poor quality).
Increasingly there is a drumbeat for change. Prospects for change depend on the extent of political will (health care is, after all one-sixth of the economy) and in current health reform, health care firms and their lobbyists are spending an estimated $1.5 million per day. Part of the basis of change lies in finding the right methods of paying for care that, once operationalized, have the power to incentivize health care providers to behave differently. But part of what must happen involves changing


36 See Orszag and Ellis, supra note 34, at 1793-95. In 2007, total health care spending accounted for nearly 16% of the nation’s gross domestic product (“GDP”), compared to 8% of the U.S. economy in 1975. See id. at 1793. It is especially significant that the bulk of this spending growth, however, is not a result from an increase in disease prevalence throughout the population, rather the increase stems from the continued development of new medical technology. Id. at 1794. Other factors affecting this rapid growth of costs include health plans adopting less aggressive forms of management and the declining proportion of costs paid out-of-pocket. Id.

37 See Dan Eggen, Health-Reform Foes Draw Industry Donations, WASH. POST, July 27, 2009, http://voices.washingtonpost.com/health-care-reform/2009/07/health-reform_foes_draw_industry.html (noting dramatic political influence of the health care sector). The Congressional Budget Office estimates that the share of the economy consumed by health care will increase to 20% by 2016. See Orszag & Ellis, supra note 34, at 1793. It is especially significant that the bulk of this spending growth, however, is not a result from an increase in disease prevalence throughout the population, rather the increase stems from the continued development of new medical technology. Id. at 1794. Others factors affecting this rapid growth of costs include health plans adopting less aggressive forms of management and the declining proportion of costs paid out-of-pocket. Id. The public portion of health care expenditures is also growing rapidly; federal forecasts predict that federal, state, and local funds will account for 49% of the overall health care bill by 2016. See Siegel, supra note 19, at 646. Federal spending alone on Medicare and Medicaid reached 4.6% of the GDP in 2007, and the CBO expects the rate to reach 5.9% of the GDP by 2017, an increase of about 30% in ten years. See Orszag & Ellis, supra note 34, at 1793.

38 See de Brantes et al., supra note 7, at 1033-34; James C. Robinson, Slouching Toward Value-Based
medical culture, which also means realignment of the legal incentives for change, which both codify culture and undergird its conduct. In this regard, antitrust represents one of the great fields of law that determines the environment in which medical care is practiced and that all too often can be cited as a basis for the failure of collaboration within a market. The problem today is that it is too easy for hospitals, insurers, and health care professionals (or more precisely, their lawyers) to point to antitrust law as a legal barrier to change.

The specter of antitrust violations threatens to stifle systemic innovations among people and entities who otherwise are competitors but who join together for the common good. To be sure there are isolated examples, such as a recently reported story on a joint effort by physicians in Cedar Rapids, Iowa, to reduce their collective use of Computed Tomography ("CT") scans for reasons of cost, quality and patient safety. While the state of Iowa could pass a law directing all physicians who use CT scans to reduce their use to published metrics developed by a public health care authority, validating every form of collective health care conduct through the state action doctrine is not a practical solution, and it certainly is inconsistent with the open spirit of collective action and innovation that lies at the heart of American culture. It is too easy to imagine physicians in another town being counseled not to meet to discuss how to collectively reduce their use of CT scans for fear that some CT diagnostic center will sue, claiming collusive conduct aimed at reducing access to patients.

Another reason underpinning this new enthusiasm for collaboration comes with the advent of enablers of collaboration such as new payment methods and HIT, which is poised to spread as a result of federal legislation enacted in 2009 that authorizes the investment of sums exceeding $45 billion by 2019. Thus the question becomes, will medicine be pushed or pulled toward change? HIT will make it possible to know much more about how health care functions within and across markets and provide the data needed to develop innovations in practice and payment that foster quality and efficiency. To be sure, some of this knowledge will be the result of state action, that is,

40 See Gawande, supra note 8.
42 See generally id.
the mandatory reporting of data to the government; indeed, it is the natural instinct among competitors—not to mention health care providers concerned about various forms of liability—to shield information as much as possible. A long road lies ahead in the effort to achieve nationwide health information access and transparency. Nonetheless, there are markets in which competitors do, in fact, show real interest in joining forces to share health information as a means of improving quality and efficiency. How to encourage this voluntary conduct becomes an important policy goal of reform.

It is our thesis that even as the Obama Administration moves more strongly to foster competition, the Federal Trade Commission and the Department of Justice (the “agencies”) should simultaneously look for ways to clarify those situations that, consistent with the Statements of Antitrust Enforcement Policy in Health Care (“Statements”), do not raise the specter of anticompetitive conduct, particularly with respect to cross-competitor health care collaborations that can foster both greater levels of transparency about health care cost and quality as well as greater levels of clinical integration among providers. The most urgent need is to encourage the type of collaboration that ultimately leads to cost containment and efficiency, even if there is a somewhat elevated risk of anti-competitive conduct in the short-term. This is because on its own, the health care industry has every financial incentive currently to be inefficient, and the types of efficiency-enhancing collaboration that have evolved in other industries appear stymied where health care provider conduct is concerned.

hhs.gov/recovery/11_healthit.asp (last visited Nov. 12, 2009) (summarizing Health Information Technology and its benefits).


49 See Gawande, supra note 8 (highlighting that physicians and hospitals make a good deal of income from the system as it stands, which does not create any incentive to improve matters).

Even as the Obama Administration seeks to increase antitrust enforcement across all sectors of the economy, the opportunity to encourage collaboration among health care competitors should not remain unaddressed. The Statements, expanded in 1996, permit certain types of clinical integration and information sharing activities. Yet in the ensuing decade, only one organization requested and received an agency advisory opinion regarding the legality of the organization's clinical integration plan. Over that same time period, the agencies initiated and settled by consent decree approximately forty-one enforcement cases against hospital-contracting and physician-contracting networks for illegal horizontal price-fixing as a result of collective bargaining on behalf of their members.

Since 2007, however, the agencies have issued three advisory opinions addressing the legality of specific clinical integration models that included the joint negotiation of price and found that all three, on their face, were likely in compliance with antitrust law, while maintaining the right to revisit the issue if the physicians did not act as they described in their integration plans. This slight uptick in clinical integration AM. MED. ASS'N. 1, 83 (2001); Choudhry & Brennan, supra note 5, at 1143.

51 See STATEMENTS, supra note 47, at 61.

52 Letter from Jeffrey W. Brennan, Assistant Director, Bureau of Competition, Federal Trade Commission, to John J. Miles, Ober, Kaler, Grimes & Shriver (Feb. 19, 2002), available at http://www.ftc.gov/bc/adops/medsouth.shtm. This organization, MedSouth, Inc., is a physician independent practice association located in Denver, Colorado. Id. MedSouth currently includes approximately 432 physicians in 216 practices, and involves partial integration among these physicians, which has been shown to have the potential to increase the quality and reduce the cost of medical care. Id.


can be attributed to physicians’ desire to gain stronger bargaining power against the powerful health insurance industry through the joint negotiation of price that clinical integration allows, and to the fact that the clinical integration model is proving attractive to provider groups seeking to foster changes in benefit, cost-sharing, and payment design that more appropriately aligns financing with high quality clinical care. These agency opinions provide a blueprint for a successful clinical integration program. However, a tremendous amount of uncertainty still exists regarding the antitrust assessment of clinically integrated physician joint ventures.

This article argues that with more guidance from the government in the form of an update to the 1996 Statements clarifying both the requirements and prohibitions for information sharing and clinical integration in an era of health reform, providers and insurers will proceed with, and the agencies will approve of, more collaboration and clinical integration models thus positioning the health care system to achieve the efficiencies and cost savings that such arrangements will bring. As useful as these statements are, they were drafted nearly fifteen years ago, well before the imperative of system-wide health care quality improvement and health information sharing had become goals in their own right.

As the current era of health reform has come to increasingly focus on efforts to improve quality and efficiency while reducing disparities in health care, this means more than simply reducing the price of treatments and procedures. We argue here for an approach to antitrust policy and enforcement that takes a longer-term view as well. In an ideal world, all health care would be delivered through the types of vertically integrated delivery systems envisioned a generation ago by Professor Alain Enthoven, with care furnished on a staff-model basis that depends on salaried health


professionals.\textsuperscript{58} The health care system has to evolve toward one that identifies inefficiencies and savings opportunities and shares best practices.\textsuperscript{59}

Insurance payment reform is part of the answer including value-based purchasing and pay-for-performance, along with the use of tiered network arrangements that encourage use of lower cost providers, bundled or global case rates, and mandatory reporting on the quality of care provided.\textsuperscript{60} Public insurers such as Medicare and Medicaid have experimented with such arrangements, and the large health benefit companies that sell health care products to employer-sponsored health care plans have sped forward with initiatives aimed at fueling the competitive benefits of the financial incentives offered.\textsuperscript{61} In turn, the health reform legislation has shown willingness to experiment with clinical integration as part of public insurance reforms.\textsuperscript{62}

But while economic incentives from payers are essential, they are not enough in our view. Physicians, hospitals, and other health care providers must be directly encouraged to change the culture of practice, to become more collaborative and more transparent, with clinical integration as the chief goal of organized medical practice.\textsuperscript{63} The efficiency-enhancing mechanisms that go along with successful clinical integration have the potential to bring down costs,\textsuperscript{64} even in the face of providers' joint negotiation of price, by reversing health care's perverse incentive to pay providers for each

\begin{itemize}
\item \textsuperscript{58} See generally Alain Enthoven, Consumer Choice Health Plan (I), 298 NEW. ENG. J. MED. 650 (1978); Alain Enthoven, Consumer Choice Health Plan (II), 298 NEW ENG. J. MED. 709 (1978). Alain Enthoven is a Stanford economist who has studied the nation's health care system for more than thirty years. See Janet Rae-Dupree, Disruptive Innovation, Applied to Health Care, N. Y. TIMES, Jan. 30, 2009, available at http://www.nytimes.com/2009/02/01/business/01unbox.html?_r=1&em. Professor Enthoven advocates letting consumers choose between traditional fee-for-services plans and less expensive integrated systems, then letting consumers pocket the difference in premiums. Id. He has said, "Medicine is a team sport. It takes an integrated system to keep the patient at the center of it." Id.
\item \textsuperscript{59} See Brook, supra note 25.
\item \textsuperscript{60} See Porter, supra note 35, at 111.
\item \textsuperscript{61} See William M. Sage & Dev N. Kalyan, Horses or Unicorns: Can Paying for Performance Make Quality Competition Routine?, 31 J. HEALTH POL. POL'Y & LAW 529, 531 (2006).
\item \textsuperscript{62} H.R. 3200, 111th Cong. §§ 1301-1310 (2009) (amending Social Security Act § 1866 D(a)(1)-(3)).
\item \textsuperscript{63} See Gawande, supra note 8.
\item \textsuperscript{64} See Gosfield, supra note 7; Alice Gosfield, The PROMETHEUS Payment Program: A Legal Blueprint, HEALTH L. HANDBOOK § 3:14 (Thomson/West ed., 2007) [hereinafter Gosfield, PROMETHEUS]; Porter, supra note 35, at 109; THOMAS ROSCH, FED. TRADE COMM'N, REMARKS AT AMERICAN HEALTH LAWYERS ASSOCIATION, ABA ANTITRUST SECTION AND ABA HEALTH LAW SECTION'S 2007 ANTITRUST IN HEALTH CARE: "CLINICAL INTEGRATION IN ANTITRUST: PROSPECTS FOR THE FUTURE" (Sept. 17, 2007), http://www.ftc.gov/speeches/rosch/070917clinic.pdf; Leibenluft & Weir, supra note 57.
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In this article we focus on two specific types of conduct. The first is the sharing of health care cost and quality information among competitors in order to spur value-based purchasing strategies. The second is the clinical integration of physician practices, even in the absence of financial integration and without the sharing of the types of overt financial risks associated with the Statements, such as fixed capitation payments for the care of a population, the most commonly recognized form of financial risk sharing.

Part II sets forth the legal underpinnings of federal antitrust law. Part III discusses value-based purchasing and the application of antitrust law to the sharing of information among competitors about these types of programs. Part IV analyzes four recent agency opinions discussing different clinical integration models and provides insight as to where the antitrust pitfalls may lie. This Part also attempts to capture the blueprint of successful clinical integration under antitrust law, as set forth by the agencies in these opinions as well as other statements and guidances, and points out where significant ambiguities still exist. Part V explains the proposed establishment of Accountable Care Organizations and suggests that a real health reform opportunity exists to link federal antitrust policy on clinical integration to certification as an ACO provider. We conclude with a discussion of the importance of further guidance from the agencies in order to maintain reform.

II. General Antitrust Principles

In 1975, the U.S. Supreme Court made clear that federal antitrust laws aimed at regulating price-fixing applied to the learned professions, including health care. Ruling that the "nature of an occupation, standing alone, does not provide sanctuary from...[antitrust law], nor is the public-service aspect of professional practice controlling in determining whether [the law] includes professions," the Court laid the groundwork.

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65 See Gawande, supra note 8; Fisher & Wennberg, supra note 8; Statements, supra note 47. But see Statement of Thomas L. Greaney, supra note 6, at 6.
66 See Goldfarb v. Va. State Bar, 421 U.S. 773, 787 (1975). The issue, one of first impression before the Supreme Court, was whether antitrust laws applied to the services performed by those in learned professions (specifically lawyers). Id. at 780. The district court held antitrust laws did apply to learned professions, while the appellate court reversed, holding those in learned professions were exempt from the Sherman Act. Id. at 779-80.
67 See Id. at 787 (citing United States v. Nat'l Ass'n of Real Estate Bds, 339 U.S. 485, 489 (1950); Associated Press v. United States, 326 U.S. 1, 7 (1945)). The court reasoned that Congress intended the Sherman Act to be broad, as evidenced by the statute's plain language which contains no exceptions. Id.
for the application of horizontal price-fixing prohibitions to medicine several years later.\textsuperscript{68} Since then, the Court has consistently rejected attempts to create special antitrust exemptions for the professions even when presented with evidence that the market for professions operates differently from other markets,\textsuperscript{69} essentially leaving the task of interpreting the intricacies of the law as applied to the field of medicine to the enforcement agencies. As a result, antitrust law and health care have had an uneasy relationship for decades.\textsuperscript{70}

At the same time, many observers have underscored the distinct qualities that make the buying and selling of health care—the single largest part of the economy\textsuperscript{71}—dissimilar to buying other consumer goods and services. Unlike other goods and services, health care is not perceived by patients as fungible; that is, one doctor does not equate to another if the price is right, as in the case of crude oil. Health care is distinguished by its very lack of fungibility, by a special relationship that governs patients and health professionals. Economists would say that this special relationship persists because of the asymmetry of information that has historically characterized this relationship.\textsuperscript{72} Most lay people would say that patients never could possess the information held by doctors and that the very essence of medicine rests on the receipt of care from highly trained professionals with a fiduciary relationship to their patients. Even as an age of consumerism has produced an explosion of information and spurred a vastly expanded role for patients in their own health care, the type of idealized buyer/seller relationships that underlie market theory\textsuperscript{73} are lacking in health care. Thus, while patients and consumers are far more knowledgeable today, the roles and duties of

\textsuperscript{68} See Arizona v. Maricopa County Med. Society, 457 U.S. 332, 348-49 (1982) (refusing to expand on the possibility that physicians and the learned professions could be analyzed differently as suggested by the Court in \textit{Goldfarb}).


\textsuperscript{73} See Paul Krugman, \textit{How Did Economists Get It So Wrong?}, N.Y. TIMES, Sept. 6, 2009, at MM36.
health professionals in society remain special ones, and the physician-patient relationship is so deeply embedded as to seemingly be insulated from even the most ardent calls for economic reforms.\textsuperscript{74} For this reason, the dance between antitrust and medicine has evolved into a search for compromises between the desire for a competitive marketplace on the one hand, and a demand for a zone of autonomy for medicine on the other.

The basic objective of antitrust law is to eliminate or prevent those practices that interfere with free competition,\textsuperscript{75} and therefore the antitrust laws (the Sherman Act, the Clayton Act, and the Federal Trade Commission Act)\textsuperscript{76} focus on certain types of conduct. Some actions are considered \textit{per se} unlawful because the behavior is deemed to be excessively damaging to the economic and competitive interests in a given market, such as a group of providers or insurers who join forces to fix the price at which they will buy or sell certain products.\textsuperscript{77} Another type of prohibited conduct involves practices that while not \textit{per se} unlawful (i.e., do not involve providers or insurers literally sitting in a room and agreeing on the price they will charge or pay) nonetheless are considered to have the effect of impeding competition in a community unless justified on the basis that such conduct also promotes a broader social good.\textsuperscript{78} This latter type of conduct is analyzed under a \textit{rule of reason} analysis.\textsuperscript{79} In a rule of reason case, unlike a \textit{per se} case, extensive evidence is considered, and the court will weigh the evidence to determine if the social good outweighs the anticompetitive risks.\textsuperscript{80} These laws are designed to encourage vigorous competition in an environment in which business entities have the full opportunity to compete for consumers on the basis of quality,

\textsuperscript{74} \textit{See} U.S. DEP'T OF JUSTICE, \textit{infra} note 22.
\textsuperscript{75} \textit{See} N. Pac. Ry. Co. v. United States, 356 U.S. 1, 4-5 (1958).
\textsuperscript{77} \textit{Arizona}, 457 U.S. at 345. See ABA SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS ch. I.B.3. (6th ed. 2007).
\textsuperscript{79} \textit{See} Standard Oil Co. v. United States, 221 U.S. 1, 66 (1911) (establishing that the standard of illegality under the Sherman Act is the rule of reason, i.e. only those restraints on trade which are unreasonable, as applied at common law, are prohibited). This standard was then refined by \textit{Chicago Bd. Of Trade}, which established the test as “whether the restraint imposed is such as [it] merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.” \textit{Chicago Bd. of Trade}, 246 U.S. at 244.
service, and price. In the context of collaboration among payers or providers of health care services in establishing innovative payment reforms or clinical integration models, Section 1 of the Sherman Act is most relevant.

The Sherman Act

Section 1 of the Sherman Act states that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several states, or with foreign nations, is declared illegal." The Supreme Court has interpreted this provision to render unlawful only those restraints of trade that unreasonably restrain competition. Three elements must be established to prove a violation of Section 1 of the Sherman Act: (1) the existence of a contract, combination, or conspiracy among two or more separate entities that (2) unreasonably restrains trade and (3) affects interstate or foreign commerce. Section 1 of the Act does not prohibit independent action by a single entity regardless of its purpose or effect on competition. As a result, an agreement between separate entities is essential to establish liability. Such an agreement has been defined by the Supreme Court as "a unity of purpose or a common design and understanding, or a meeting of the minds in an unlawful arrangement." The Supreme Court has also stated that an illegal contract or conspiracy need not require any formal agreement but can be inferred from circumstantial evidence.

83 Id.
85 See Maric v. St. Agnes Hosp. Corp., 65 F.3d 310, 313 (2d Cir. 1995) (listing three elements and holding that first element was not met).
86 Sherman Act, 15 U.S.C. § 1 (2006). Section 2 of the Sherman Anti-Trust Act and parts of the Clayton Act, however, do reach and prohibit certain types of monopolistic practices by single entities, such as the willful acquisition or maintenance of monopoly or market power with the ability to control market prices or exclude competition in a given market. Sherman Act, 15 U.S.C. § 2 (2006); Clayton Act, 15 U.S.C. §§ 12-14, 18. Conduct amounting to refusals to deal, agreements to foreclose competition, leveraging power in one market to gain power in another market, tying arrangements, and predatory pricing are examples of the types of behaviors that may violate antitrust law's monopoly prohibitions. Sherman Act, 15 U.S.C. § 2.
89 See Eastern States Retail Lumber Dealers Ass'n v. United States, 234 U.S. 600, 612 (1914); Nurse Midwifery Assocs. v. Hibbett, 918 F.2d 605, 616 (6th Cir. 1990) (elements of conspiracy
Proof of Concerted Activities

The most common antitrust violations of Section 1 of the Sherman Act result from "horizontal" arrangements that involve concerted or collusive activities by competitors in a given market. Whether enforcement is sought by the government or private litigants, a plaintiff must prove not only that the defendants are legally capable of conspiring (i.e., the alleged collusive activity did not occur between a parent company and its subsidiary), but also that they actually did so. In the absence of a formal agreement to collude, the Supreme Court has placed reasonable limitations on the range of permissible inferences from ambiguous evidence of an agreement or conspiracy. Thus, the relevant inquiry becomes whether the defendant had any rational motive to conspire, and whether the defendant's conduct was consistent with its own independent interest.

While evidence of collusive action gives rise to liability exposure, there are defenses. For example, defendants may be able to avoid liability by showing that they had no rational motive to conspire, or the entity's conduct can be plausibly explained, and thus the conduct is deemed not to rise to the level of a Section 1 violation. Furthermore, a pattern of uniform business conduct among competitors known as "conscious parallelism" does not, standing alone, run afoul of the antitrust laws. Parallel behavior by itself does not prove a conspiracy; plaintiffs must offer several "plus charge may be inferred from behavior); Oltz v. St. Peter's Comty. Hosp., 861 F.2d 1440, 1450 (9th Cir. 1988) (direct evidence of conspiracy rare); Key Enters. of Del., Inc. v. Venice Hosp., 919 F.2d 1550, 1563 (11th Cir. 1990) (conspiracy may be proved by surrounding circumstances); see also Monsanto, 465 U.S. at 764.


91 See American Tobacco, 328 U.S. at 814-15; Monsanto, 465 U.S. at 765.

92 See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); see also Corner Pocket of Sioux Falls, Inc. v. Video Lottery Techs., 123 F.3d 1107, 1112 (8th Cir. 1997) (refusing to infer conspiracy where "objectively observable market conditions are consistent with defendants' assertions" of unilateral and independent actions).

93 Matsushita Elec. Indus., 475 U.S. at 588.

94 See Corner Pocket of Sioux Falls, Inc. v. Video Lottery Techs., 123 F.3d 1107, 1112 (8th Cir. 1997). The court concluded that the district court properly looked to observable market conditions to determine that the defendant's acted unilaterally in selling and marketing the video lottery systems. Id.

95 See Theatre Enters. v. Paramount Film Distribution Corp., 346 U.S. 537, 541 (1954) (holding that proof of parallel action in itself does not constitute anti-trust action); Blomkest Fertilizer, Inc. v. Potash Corp. of Saskatchewan, 203 F.3d 1028, 1051 (8th Cir. 2000) (noting that defendants knowledge of prices of each other's prices was not sufficient to determine anti-trust activity).
factors" in combination with conscious parallelism to prove an inference of coordinated action. These "plus factors" are often other facts and circumstances that support the claim that a conspiracy has occurred. The crux of this defense will hinge on whether any meeting of the minds occurred with regard to actual implementation and roll-out related to the setting of price.

Unreasonable Restraint on Trade

Once it has been determined that the defendants have the legal capacity to conspire and that an unlawful agreement exists, the effect of that agreement must be considered to determine whether it restrains competition unreasonably. The courts generally use one of two methods to make this determination depending on the nature of the agreement at issue. As noted above, certain categories of restraints, such as horizontal price-fixing, group boycotts, bid rigging and market-allocation agreements are considered "per-se illegal." That means that these activities 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 or their purpose. However, the prevailing standard for assessing the effect on competition of most categories of restraints is the "rule of reason," which requires an analysis of the restraint's effect on competition in a relevant market. The rule of reason is applied in situations "where the economic impact of certain practices is not immediately

96 See Twombly v. Bell Atl. Corp., 425 F.3d 99, 114 (2nd Cir. 2005) (dismissing the case based upon a failure to state a claim upon which relief can be granted).
97 Id.
98 See Fed. Trade Comm'n v. Ind. Fed'n of Dentists, 476 U.S. 447, 459 (1986) (stating the test for the "Rule of Reason"). The Rule of Reason is determined by whether the restraint in question merely regulates and possibly promotes competition or whether it suppresses or destroys competition. Id.
99 See, e.g., Arizona, 457 U.S. at 343 (noting the two methods of determining whether an unlawful agreement exists). The rule of reasonableness requires an elaborate inquiry. Id. Judges often lack the expertise in the market structure. Id. After an experience with a "particular type of restraint," courts are able to presume with confidence that the restraint is within violation of the rule and create a presumption against reasonableness. Id. at 344.
100 See Arizona, 457 U.S. at 345 (stating price-fixing illegal where done by controlling players in the business); see also Northern Pac. Ry. Co., 356 U.S. at 5 (summarizing general court findings of unlawful practices including division of markets and boycotts); Fed. Trade Comm'n, 476 U.S. at 458. See generally United States v. Socony-Vacuum Oil Co., 310 U.S. 150 (1940) (finding buying programs engaged in by defendant a form of price-fixing).
101 See Orszag statement infra note 133; see also 17 AM. JUR. 2D Monopolies and Restraints of Trade § 795 (2009) (describing generally per se illegality based in "pernicious" impacts on trade); Fed. Trade Comm'n, 476 U.S. at 458.
obvious."\textsuperscript{103}

Of course, defendants in antitrust actions would much prefer that in evaluating a claim, a court use a rule of reason analysis, as opposed to a per se analysis, because it gives the defendant the chance to justify its actions by offering facts that are viewed as demonstrating a pro-competitive effect as a result of the agreement.\textsuperscript{104} Indeed, medicine has long argued that its pricing policies can only be judged under a rule of reason test because of the special considerations of quality and professionalism on which pricing rests.\textsuperscript{105} The issue of whether agreements over pricing should be held to a lower or higher standard of conduct lies at the heart of the dispute over how to evaluate health care in an antitrust context.

**Agreements on Price**

Of most concern for health insurance companies engaged in discussing and implementing value-based purchasing, and for physicians seeking to collectively bargain over price through clinical integration, is the danger that these activities will be considered price-fixing under the Sherman Act. Price-fixing allegations are subject to a \textit{per se} unreasonable restraint analysis, which offers the defense very little chance to defend its actions.\textsuperscript{106} Once a plaintiff can show that two or more competing insurers or independent providers tacitly or otherwise agreed to implement a payment model with agreed-upon prices for provider services, it is likely that a court will view this as price-fixing, even if indirectly so, and impose liability under the \textit{per se} rule.\textsuperscript{107}

Antitrust cases are replete with examples of agreements that were determined to be price-fixing arrangements, such as establishing minimum or maximum prices,\textsuperscript{108}

\textsuperscript{103} See id. at 459.

\textsuperscript{104} See Rome Ambulatory Surgical Ctr., 349 F. Supp. 2d at 410 (stating rule of reason allowance of argument for precompetitive justification). Defendant may defeat plaintiff's claim of illegal exclusive contracts by showing the alleged conduct was justified in its precompetitive impacts. \textit{Id.} at 411.

\textsuperscript{105} See Arizona, 457 U.S. at 348 (differentiating between professionals and nonprofessionals).

\textsuperscript{106} See Hermer \textit{infra} note 134.

\textsuperscript{107} See Anthony J. Dennis, \textit{Hospitals, Physicians, and Health Insurers: Guarding Against Implied Agreements in the Health Care Context}, 71 \textit{WASH. U. L. Q.} 115, 125 (1993) (outlining general rule of implied agreements). Implied or tacit agreements are proved by circumstantial evidence. \textit{Id.} The court considered the following factors: the course of dealings between the parties, including communications, the nature of the relationship, and the nature of previous business interactions; if an opportunity to conspire existed; parties' conduct in the marketplace; existence of an economic motive to conspire; and existence of anticompetitive conduct. \textit{Id.}

\textsuperscript{108} See generally Arizona, 457 U.S. at 347; Goldfarb, 421 U.S. at 781 (ruling on the establishment of
creating pressure to increase prices,\textsuperscript{109} stabilizing prices,\textsuperscript{110} or establishing uniform terms of sale, discount policies, or otherwise establishing an agreed-upon approach to an underlying element of the price charged.\textsuperscript{111} Exchanging information would, even if challenged, appear to be judged under the rule of reason.\textsuperscript{112} However, even under a rule of reason analysis, courts have prohibited information exchanges in industries whose structural characteristics indicate that exchanging price information is likely to have an anticompetitive effect.\textsuperscript{113} That is, courts can at some point view the exchange of information as suspicious in its own right, thus underscoring the need for further clarity and certainty in the field.\textsuperscript{114} Thus, an exchange of price information that is not part of a price-fixing scheme may be legal if its value for quality purposes outweighs any likely anti-competitive effects.\textsuperscript{115} At the same time, the very nature of a "rule of reason" analysis—a case by case review of the facts—suggests the inherent challenges in applying antitrust law to a fast-evolving field of health care, especially when dealing with matters of first impression like value-based purchasing arrangements.\textsuperscript{116}


\textsuperscript{110} United States v. Container Corp. of Am., 393 U.S. 333, 337-38 (1969) (ruling on stabilizing prices). The court held price to be "too critical, too sensitive" to restrain with price fixing. \textit{Id.}

\textsuperscript{111} See Catalano, Inc. v. Target Sales, Inc., 446 U.S. 643, 650 (1980) (concluding \textit{per se} illegal price fixing existed where wholesalers agreed to stop extending trade credit to retailers); Vandervelde v. Put & Call Brokers & Dealers Ass'n, 344 F. Supp. 118, 136 (S.D.N.Y 1972) (concluding \textit{per se} illegal price fixing existed where a professional association required members to sell options to one another at a discount).

\textsuperscript{112} See United States v. U.S. Gypsum Co., 438 U.S. 422, 441 n.16 (1978) (finding exchanging information as not necessarily having anticompetitive effects); United States v. Citizens & S. Nat'l Bank, 422 U.S. 86, 113-14 (1975) (finding corresponding associate programs not necessarily anticompetitive where the programs had a need to interact on an active level).

\textsuperscript{113} See, e.g., \textit{Container Corp. of Am.}, 393 U.S. at 337-38 (prohibiting price verification practices in concentrated industry). The court held where the market had few competitors and consumers purchases were inelastic and based on short-term need, price verification created illegal anticompetitive effects. \textit{Id.}

\textsuperscript{114} \textit{Id.} at 337 (finding market stabilization a form of manipulation). \textit{See also Socony-Vacuum Oil Co.,} 310 U.S. at 223.

\textsuperscript{115} \textit{See U.S. Gypsum Co.}, 438 U.S. at 441 n.16 (describing situation where exchange of price data is not anticompetitive but rather may increase economic efficiency and actually increase market competition); \textit{see also Citizens & S. Nat'l Bank}, 422 U.S. at 113 (dissemination of price information is not itself a \textit{per se} violation of antitrust law).

\textsuperscript{116} \textit{See U.S. Gypsum Co.}, 438 U.S. at 476-77. The rule of reason requires an element in addition to proof of an agreement between major producers to exchange current price information. That element can be either an actual market effect or an express purpose to affect market price. \textit{See also Citizens & S. Nat'l Bank}, 422 U.S. at 113 (applying rule of reason to lawfulness of restraint in case).
Statements of Antitrust Enforcement Policy in Health Care

To complicate matters, the antitrust implications of an agreement on price, whether in the form of an outright price-fixing scheme or a tacit agreement to pursue certain payment arrangements, has become exceedingly difficult to determine in today's health care industry, because of the blizzard of initiatives aimed at reducing cost and improving quality through value-based purchasing. Individual Practice Associations ("IPA"), Preferred Provider Organizations ("PPO"), Physician-Hospital Organizations ("PHO") and other entities not licensed as insurers often sell their services to health insurers and employee health benefit plans. If less than fully clinically or financially integrated, these entities may face significant antitrust risk because of their structure.

Over the years, Congress, federal and state regulators, and the courts have developed certain exemptions and "safety zones" to adjust the law of market competition for special markets and market conditions in which competition is thought to be less desirable. Chief among the areas that have experienced a more customized approach to antitrust law is health care, for which the United States Department of Justice and the Federal Trade Commission have developed special Statements of Antitrust Enforcement Policy.

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117 See Agency for Health Care Research and Quality, U.S. Dep't of Health & Human Services, A Guide to Evaluating the Impact of Value-Based Purchasing, http://www.ahrq.gov/about/cods/valuebased/evalvbp1.htm#whatisvbp (last visited Nov. 2, 2009). A Google search of "value-based purchasing" at the HHS website turns up several thousand separate hits with numerous documents regarding value-based purchasing and "how to" guides on the activity. Id. The Agency for Health Care Research and Quality defines "value-based purchasing" as the act on the part of buyers of holding health care sellers "accountable for both cost and quality of care." Id. Thus, a value-based purchasing initiative would bring together information on the quality of health care, including patient outcomes and health status, with data on the dollar outlays going towards health. Id. It focuses on managing the use of the health care system to reduce inappropriate care and to identify and reward the best-performing providers. U.S. Dep't of Health & Human Services, supra note 117. This strategy can be contrasted with more limited efforts to negotiate price discounts, which reduce costs but do little to ensure that quality of care is improved. Id.

118 See Leibenluft & Weir, supra note 57.

119 See id. (discussing the number of successful antitrust prosecutions against IPAs, etc. for price fixing since 2002).

120 See Blumenthal, supra note 69, at 11-12. The Federal Trade Commission has partnered with the Department of Justice to establish a balancing test to evaluate physician network joint ventures that may yield impressive efficiencies. Id. at 11. The FTC may apply the balancing test if the physicians' integration is likely to produce significant efficiencies for consumers and price agreements are necessary to accomplish that. Id.

121 See Thomas L. Greaney, Whither Antitrust? The Uncertain Future of Competition Law in Health Care, 21 HEALTH AFF. 185, 185-196 (2002).
Enforcement Policy in Health Care ("Statements"). The Statements represent a major effort on the part of the agencies to apply antitrust principles to medicine, taking into account the unique set of circumstances that we have described herein.

But while these special rules may modify classic antitrust principles, they do not, by any means, take health care purchasing out of the field of antitrust. In fact, in recent years the federal government has sought to broaden the reach of antitrust law in the health care sector, taking the form of more aggressive pursuit of physicians and hospitals for allegedly unlawful restraints of trade through conspiracies to set prices in the case of physicians or through anticompetitive mergers that drive up market prices in the case of hospitals. The federal government also has conducted extensive policy analyses examining the effects of limited competition on health care cost and quality. However, there is no general, express provision in the 1996 Statements permitting the types of expanded collaborations that one might envision in an era in which the expanded use of health information has become a driving national policy goal.

The agencies' Statements recognize the pro-competitive potential of information exchanges, but also warn that such exchanges may in certain cases increase the likelihood of collusion on matters such as price, output or other competitively sensitive variables. These Statements create antitrust safety-zones for certain categories of information exchange, and conduct that falls within a safety-zone will avoid an agency finding of per se antitrust liability. Central is the goal of financial integration, underscored in the Statements as the basis for a safety-zone exemption. But short of financial integration, the Statements do provide for horizontal conduct in certain limited ways by clarifying the application of the rule of reason analysis for clinically integrated

122 See Statements, supra note 47.
123 See id.
126 See generally IMPROVING HEALTH CARE, supra note 22. Several sections discuss the research conducted to determine the effects of such limited competition. Id.
128 See Statements, supra note 47.
129 See id.
130 See id.
III. Information Sharing for Value-Based Purchasing

Public and private health insurers have a high degree of interest in “value-based purchasing” innovations involving the use of provider performance data to assess quality and develop benefit, pricing, and payment policies that reward high performance and incentivize improvements. Extensive evidence shows high variability in costs and quality among U.S. health care markets. Most markets contain thousands of individual health plan sponsors (e.g., public and private employers, Medicaid agencies, and Medicare) who utilize multiple health benefit service companies to either insure or administer their plans. Given the shared interest in raising quality and reducing costs, it makes sense for health insurers, providers, employer sponsors, and others to collaborate on efforts to set common performance expectations, share information about actual health care performance, costs, and pricing, and seek system-wide improvements in quality and efficiency. The concept of “value-based purchasing” has been a formal federal policy focus for several years, and the United States Department

131 See id.
of Health and Human Services ("HHS") has attempted to spur value-based purchasing interest. These types of payment experiments are designed to improve health care quality and increase the transparency of health care pricing information in order to increase health care efficiency.

An important question is how antitrust law would treat efforts by health insurers who otherwise are competitors but who desire to share information on quality and efficiency benchmark measures, compare provider network performance on these benchmark measures, and identify opportunities for cost savings through both investments and a restructuring of cost management approaches for both acute and chronic conditions. As noted, antitrust law prohibits conduct among competitors that seeks to restrain trade, but this prohibition certainly does not proscribe all interactions between competitors in a given market. Indeed, carefully crafted forums designed to promote value-based purchasing by providing quality information and technical support to the participants—even if competitors—appear to be legal under antitrust law as long as the participants do not collectively set uniform prices, fees, or bonus amounts.

Thus, where competitors make the choice to collaborate through exchange of non-pricing information, no provision of antitrust law would appear to bar it.

138 See de Brantes et al., supra note 7, at 1033 (describing the Prometheus payment model). The Prometheus payment model is being developed for payers to allow such payers to know what ought to be paid for efficient care. Id. It is precise because there are a dearth of such ready-made tools that insurers might consider collaborating on to develop common data bases, not unlike the Ingenix data base that, despite its flaws, serves the same purpose of telling insurers what they should pay for out-of-network care. See id. (describing payment model). See also supra notes 90-108 and accompanying text (discussing collusion and restraints on trade).
140 See U.S. Gypsum Co., 438 U.S. at 443 n.16 (permitting exchange of information in certain
Because the overarching aim of antitrust law is free and open markets in which competition can flourish, information exchange that spurs innovation can promote competition by revealing important strategies and pathways to system efficiencies and quality improvement. Indeed, short of outright government interventions that compel the reporting of detailed practice input and output information in geographic markets and also make that information publicly available for widespread use in coverage and payment design, incentivizing private cross-collaborations within and across markets will be essential to the achievement of higher value care.

At the same time of course, collaborations among competitors must be undertaken with caution. To the extent that separate competing health care entities—whether insurers, health plan administrators, or health care providers—agree tacitly or otherwise on the structure and pricing of provider agreements, the elements of a Section 1 violation of the Sherman Act appear to be in place absent any defenses. In the same vein, were competing providers to jointly agree to financial bargaining strategies without sufficient clinical integration, such conduct would appear to violate the antitrust principles as well. Indeed, it was concerted provider action related to the pricing of health care that led to the Supreme Court’s seminal decision in Arizona v Maricopa County Med. Soc., in which the Court found pricing efforts among horizontal health care competitors, even where ostensibly linked to the advancement of health care quality goals, to constitute a per se violation of Section 1 of the Sherman Act. In the wake of Maricopa, as discussed above, the agencies issued Statements of Antitrust Enforcement Policy in circumstances; see also Arizona, 457 U.S. at 366-367 (Powell, J., dissenting) (noting the need for tailoring antitrust inquiry into per se illegality to industry in question). In the context of complex medical arrangements, assumptions about collaboration are inherently detrimental to consumer welfare and may be imperfect. Id. See also Monroe & Seitz, supra note 139, at 85 (noting permission).

See Northern Pac. Ry., 356 U.S. at 4-5 (discussing purpose of Sherman Act); Arthur N. Lerner et al., Joint Ventures in Health Care: An Antitrust Analysis, 73-80 (American Bar Association, 2000) (drawing a fine line between a characterization of information exchange through joint ventures as pro-competitive and a determination that venture participants are cooperating too much).

See Socony-Vacuum Oil Co., 310 U.S. at 213 (prohibiting uniform price-fixing); supra notes 105-116 and accompanying text (discussing price fixing claims and possible defenses).

See Gypsum Co., 438 U.S. at 441-43 (announcing Sherman Act not violated absent anticompetitive intent). Lack of integration can be demonstrative of anticompetitive intent because collaboration and data exchanges are viewed as forming a gray zone between clearly per se illegal activity and efficiency enhancing practices in which it can be difficult to determine whether a company is purposefully engaging in unlawful collusive behavior. Id. at 441 n.16.

Id. at 332.

Idaho, 457 U.S. at 349-51 (announcing per se rule).
Health Care in order to clarify the types of health care organizations and collaborative activities that would be considered permissible under antitrust law. Several Statements are applicable to conduct that involves information sharing about value-based purchasing strategies among horizontal competitors.

Statement 4 addresses the government’s “[e]nforcement policy on providers’ collective provision of non-fee-related information to purchasers of health care services.” The antitrust safety-zone provided by this Statement allows providers to collectively give to purchasers “underlying medical data that may improve purchasers’ resolution of issues relating to the mode, quality, or efficiency of treatment.” The collection of outcome data from independent physicians about a particular procedure that the providers believe should be covered, and the provision of that information to purchasers, falls within the safety zone and is not a per se violation of antitrust law. In addition, the antitrust enforcement agencies will not challenge “providers’ development of suggested practice parameters (standards for patient management developed to assist providers in clinical decision-making) that also may provide useful information to patients, providers, and purchasers.” The agencies believe that this type of concerted conduct by physicians poses little risk of restraining competition and in fact has the potential to increase quality and efficiency, thereby promoting competition. Statement 4 warns, however, that the safety-zone does not apply to the extent that this activity is used by providers to coerce purchasers’ decision-making by threatening to boycott a plan that does not adhere to the providers’ joint recommendation.

Statement 5 also has relevance. This statement addresses the government’s “[e]nforcement policy on providers’ collective provision of fee-related information to purchasers of health care services.” Regardless of the structure of the provider

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146 See Statements, supra note 47, at 2 (clarifying antitrust safe zones).
147 Id. at 49.
148 Id. at 5-6 (stating the Agencies will not challenge a medical sorority’s collection of outcome data absent “extraordinary circumstances”).
149 Id. at 50 (demonstrating the proposed acceptance will allow for the collection of procedural data without violating antitrust law).
150 See Statements, supra note 47, at 50 (restraining competition is of little risk and instead may improve protocols).
151 Id. at 50-51 (running a substantial risk of antitrust violations if a threat of a boycott occurs).
organization, competing providers can collectively give payers information about price or other aspects of reimbursement (such as episode-of-care cost determinations) without raising significant antitrust implications. The agencies acknowledge that "such factual information can help purchasers efficiently develop reimbursement terms to be offered to providers and may be useful to a purchaser when provided in response to a request from the purchaser or at the initiative of the providers." The agencies provide a detailed antitrust safety-zone for this type of scenario if providers satisfy the following conditions: (1) the pricing information is collected by a third-party; (2) while the payers can secure newer pricing data, any information that is shared among the providers must be at least three months old and the pricing data must reflect pricing data from at least five providers with no one provider's data representing more than twenty-five percent of that statistic; and (3) the information must be aggregated so that the recipients cannot identify the prices charged by any single physician. Thus Statement 5 allows aggregated data sharing of price-relevant data by physicians collectively to purchasers, under certain limited conditions.

Statement 6 is also relevant. This statement addresses the government's "[e]nforcement policy on provider participation in exchanges of price and cost information." Here, the antitrust enforcement agencies have created a safety-zone for "participation by competing providers in surveys of prices for health care services, or surveys of salaries, wages or benefits of personnel." The agencies believe that this information can increase competition because providers can use this information to price their services more competitively, and purchasers can use the survey data to make informed decisions about what they will buy. Specifically, to fall within the safety-zone and thereby avoid per se antitrust liability, several elements must be present: (1) the survey is managed by a third-party; (2) the information provided by survey participants is based on data more than three months old; and (3) there are at least five providers reporting data upon which each disseminated statistic is based, no individual provider's

153 Id. (qualifying for this exemption requires the meeting of several conditions).
154 Id. (referring to information concerning current and historical fees and other reimbursements, including discounts, capitation arrangements, risk-withhold fee arrangements, and all-inclusive fees). This lead to the potential of lowering costs through reimbursements. See id.
155 Id. (outlining the conditions that must be met by providers to qualify for the antitrust safety zone).
156 Id. (explaining additional allowances Statement 5 makes about data sharing).
158 Id. (describing another antitrust safety zone the agencies have created).
data represents more than twenty-five percent on a weighted basis of that statistic, and
any information disseminated is sufficiently aggregated such that it would not allow
recipients to identify the prices charged or compensation paid by any particular
provider.159 Statement 6 therefore allows, under certain circumstances, competing
providers to share among themselves—or publish for public use—specific provider
price and cost information.

Where the sharing of information occurs at the payer level, the agencies’
“Antitrust Guidelines for Collaborations among Competitors” become most
applicable.160 This document discusses the framework for evaluating agreements among
competitors that might withstand antitrust scrutiny, because the agreement is reasonably
necessary to achieve pro-competitive benefits from an integration of economic
activity.161 Here, the more factually-driven rule of reason analysis would be employed to
determine whether the pro-competitive benefits outweigh anticompetitive harms.162
The guidelines specifically mention several types of collaborative agreements that tend
to limit independent decision-making or combine financial interests and thus harm
competition: production collaborations, marketing collaborations, buying collaborations,
and research and development collaborations.163 While these guidelines are not
specifically directed at the health care industry as are the Statements and do not
specifically address value-based purchasing strategies, the fact that the agencies consider
an in-depth rule of reason appropriate in these circumstances becomes important in
guiding information sharing along these lines.164

159 Id. (outlining elements that must be met to qualify for this antitrust safety zone).
160 See U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, ANTITRUST GUIDELINES FOR
os/2000/04/ftcdojguidelines.pdf [hereinafter ANTITRUST GUIDELINES] (explaining how agencies
analyze certain antitrust issues raised by collaborations among competitors).
161 See id. at 7-25 (referring to situations in which procompetitive benefits offset anticompetitive
harm).
162 Id. at 7. Certain types of agreements that have no significant benefits and are likely to stifle
competition are presumed illegal per se. Id.
163 ANTITRUST GUIDELINES, supra note 160, at 13-15 (outlining the guidelines and the
collaborative agreements mentioned).
164 See ANTITRUST GUIDELINES, supra note 160, at 13-15 (reciting Agencies’ considerations when
forming these set guidelines).
IV. Clinical Integration

There is no question that the Statements favor financial integration, creating an exemption from liability where such integration is achieved. In this context, Statement 8 becomes highly relevant. Indeed, the original Statement 8 issued in 1994 stipulated only two pathways that providers could take to avoid antitrust problems when they sought to collectively bargain for price. One was the “messenger model,” and the other was adequate financial integration, defined as risk sharing that “provides incentives for physicians to cooperate in controlling costs and improving quality by managing the provision of services by network physicians.” In its original issuance of Statement 8, the FTC made clear that the Statement 8 antitrust safety-zones were only available for financially integrated arrangements because by definition financial integration incentivizes efficiencies.

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


167 See U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, STATEMENTS OF HEALTH CARE ANTITRUST ENFORCEMENT POLICY, available at http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm (last visited Nov. 12, 2009). The messenger model involved the use of an entity that represented the physicians and avoided horizontal price-fixing because the entity would simply “messenger” fee proposals back-and-forth between individual physicians and payers until an agreement was reached. Id.

168 See STATEMENT 8, supra note 166, at 3. Examples of financial integration include “agreement[s] by the venture to provide services to a health plan at a ‘capitated’ rate; agreement[s] by the venture to provide designated services or classes of services to a health plan for a predetermined percentage of premium or revenue from the plan; [or] use by the venture of significant financial incentives for its physician participants, as a group, to achieve specified cost-containment goals.” Id.

169 See Rosch, supra note 64, at 6 (explaining that risk sharing in “financial integration provides strong incentives for the physicians involved to cooperate in controlling costs and improving quality”).

170 Id. at 7 (noting the statements were revised and expanded to provide further guidance “based on the collective experience of the agencies”). See also STATEMENTS, supra note 47, at 88.
integration as an additional means for physician groups to avoid antitrust liability for joint negotiation of fees. Revised Statement 8 illuminates the agencies' position on what constitutes adequate clinical integration, such as to allow collection physician bargaining even in the absence of significant financial risk.

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. Critically important is the requirement that the clinical integration 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.” Revised Statement 8 offers several examples of indices of quality and efficiency improvement that in turn would justify joint contracting conduct even in the absence of financial risk-sharing including establishing mechanisms and systems to monitor and control utilization of health care services that are designed to control costs and assure quality of care; the development of practice standards and protocols to govern treatment; the regular evaluation of both individual participants' and the network's aggregate performance with respect to established quality and efficiency goals as well as the treatment standards and protocols; the ability to modify individual participants' actual practices where necessary based on the evaluations, or in the alternative, expel non-compliant physicians from the network; selectively choosing group physicians who are likely to further these efficiency objectives; the use of information systems to gather aggregate and individual data on cost and quality, the exchange of such information, and an investment of capital to purchase and maintain such systems; and the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.

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171 Rosch, supra note 64 at 7; see also STATEMENTS, supra note 47, at 93.
172 See STATEMENT 8, supra note 166, at 3-7 (outlining the agencies' analysis of physician network joint ventures that fall outside the antitrust safety zones).
173 See id. at 4 (stating that physician network joint ventures will not be viewed as per se illegal if the physicians' integration through the network is "likely to produce significant efficiencies that benefit consumers, and any price agreements . . . are reasonably necessary to realize those efficiencies").
174 Id. at 4 (establishing that physician joint ventures not involving the sharing of financial risk may still involve sufficient enough integration to show that the venture is likely to produce significant efficiencies).
175 Id. at 4-8 (describing several program arrangements that can evidence sufficient integration to warrant a rule of reason analysis). This list of indicia is not exclusive, as the Agencies will consider other arrangements that may evidence integration, focusing specifically on substance
Unlike financial integration, clinical integration achieves efficiencies through organized, interdependent, and cooperative activity among the physicians and hospitals. The FTC, as discussed below, through several advisory opinions and settlements of cases involving anticompetitive conduct, has provided some guidance as to the specific elements of a successful clinical integration arrangement that includes the joint negotiating of price by physicians with insurers, discussed below.

The problem, of course, is the current state of American medicine, which has yet to evolve into the types of fully integrated models represented in the Enthoven ideal, but rather has created instead the scattered handful of staff-model HMOs that exist in various markets in the U.S. As noted, the march toward the creation of fully integrated entities came to an abrupt halt with the managed care backlash and much of the health care system remains isolated, structurally unorganized, and susceptible to high cost, practice inefficiencies, and poor quality. Despite the emphasis on full integration, medicine has been exceedingly slow to change for technical, cost, and cultural reasons. Short of an all-out legal mandate that physicians join large practice groups as a condition of receiving payment under Medicare or other forms of federally subsidized public or private health insurance (technically and Constitutionally possible as part of health reform but politically unlikely), the question becomes how to incentivize such a shift. One answer, discussed below, is better payment to health care providers that clinically integrate. Another might be to permit entities that display indicia of clinical integration to bargain jointly with payers even in the absence of full financial integration, as long as certain conditions are met. In other words, recognizing clinical integration as justification in its own right for joint contracting could help spur movement.

Such joint negotiation of price by otherwise independent or loosely affiliated network physicians mirrors precisely the conduct deemed unlawful per se in Maricopa County as a price-fixing violation under Section 1 of the Sherman Act. Thus the
question becomes whether there are circumstances under which a rule of reason analysis might be justified when otherwise competing physicians jointly negotiate their fees with health care payers.\textsuperscript{182}

Statement 8 thus amplifies on the basic premise of the \textit{Statements} by articulating criteria related to what is needed to potentially make a rule of reason approach possible where financial integration is not present.\textsuperscript{183} For independent physicians or physician groups to jointly negotiate price legally (and thus be subject to the rule of reason and not \textit{per se} liability), they must have some level of medical practice integration—either financial or clinical—whose purpose is to achieve significant efficiencies in the provision of medical care to patients.\textsuperscript{184} That is, the joint negotiation of price must be reasonably necessary to achieve these efficiencies, rather than the main objective of the physicians.\textsuperscript{185} The exact threshold of integration (either form) required to justify ancillary collective bargaining of price by providers is determined on a case-by-case basis,\textsuperscript{186} and provider models falling below the integration threshold, as noted, run the risk of a \textit{per se} price-fixing charge.\textsuperscript{187} Providers testing new combination models need to strive for the type of integration that is likely to produce efficiencies in order to trigger a rule of reason approach.

It is worth noting that joint negotiation of price by independent physicians with health insurers is hardly a novel concept, as evidenced by the prolific development of IPAs and PHOs during the 1980s and early 1990s, designed to combat the increased bargaining power of managed care consolidation.\textsuperscript{188} These entities have attempted financial integration to legally negotiate price jointly, which requires the sharing of financial risk among the participating providers through the use of, for example, capitation programs or the significant withholding of reimbursement.\textsuperscript{189} But as noted,


\textsuperscript{183}See \textit{Statements}, supra note 47.

\textsuperscript{184}See Leibenluft & Weir, supra note 57.


\textsuperscript{187}See Leibenluft & Weir, supra note 57.

\textsuperscript{188}See Choudhry & Brennan, supra note 5, at 1141; Hellinger & Young, supra note 50.

\textsuperscript{189}See Choudhry & Brennan, supra note 5, at 1143; Hellinger & Young, supra note 50. Other successful methods of financial integration include agreements to provide services for a predetermined percentage of premium or revenue from the plan, the imposition of significant
during the last decade, risk contracting among providers has fallen into disfavor for a variety of reasons, and the number of IPAs and PHOs has decreased considerably.\textsuperscript{190} More recently the FTC has increased its scrutiny of “sham” IPAs and PHOs that the Agency claims exist only to jointly negotiate price without the necessary quality, cost, and efficiency attributes required of adequate integration of either type.\textsuperscript{191} Since 2002, the FTC has taken action against twenty-two IPAs and seven PHOs for price-fixing, and all but one of these twenty-nine organizations agreed to sign consent orders to terminate existing and cease negotiating non-risk contacts.\textsuperscript{192} In all of these cases, clinical integration was discussed as a missed opportunity for avoiding antitrust enforcement and the attendant settlements.\textsuperscript{193}

Clinical integration, as sanctioned by Statement 8, in essence mandates some level of physician interdependence in the actual provision of care to patients, that is, physicians and hospitals acting as one to improve the quality and efficiency of care, particularly in the case of complex conditions that compel cross-system action.\textsuperscript{194} This approach has been the road-less-traveled but in the view of the Agency, has the potential to create treatment and cost efficiencies sufficient to justify, if not an exemption, at least a willingness to proceed under a rule of reason approach.\textsuperscript{195} For example, where physicians can benefit from collectively developed medical protocols and streamlined information sharing through online networks, it is reasonable to conclude that such actions will increase economic efficiency, innovation, and the quality of care.\textsuperscript{196} Yet the specter of liability for horizontal price restraints never completely abates, as in a true exemption situation, because there is always the potential for cross-competitor price fixing.\textsuperscript{197}


\textsuperscript{191} See Casalino, \textit{supra} note 50, at 576.

\textsuperscript{192} See Casalino, \textit{supra} note 50, at 573-74; see also N. Tex. Specialty Physicians v. Fed. Trade Comm'n, 528 F.3d 346, 356 (5th Cir. 2008) (discussing how one IPA refused to sign a consent order).

\textsuperscript{193} See Gosfield, \textit{PROMETHEUS}, supra note 64, § 3:14.

\textsuperscript{194} See Asyltene, \textit{supra} note 176.

\textsuperscript{195} See Casalino, \textit{supra} note 50, at 573-74.


\textsuperscript{197} See Rosch, \textit{supra} note 64, at 16 (discussing issues presented to antitrust enforcers when doctors
The FTC has recognized both the advantages and risks of clinical integration coupled with providers jointly negotiating their fees, and the Agency will employ the rule of reason analysis in clinical integration cases to answer the following questions: Does the overall arrangement benefit consumers in terms of treatment and cost to a high-enough degree to outweigh the potential harms to competition, and are the collective bargaining elements of the integrated arrangement that threaten competition reasonably necessary to realize these benefits? If the answer to both questions is “yes,” then the arrangement can proceed and the joint negotiation of price by providers will not be deemed price-fixing.

A quartet of FTC rulings in recent years show the clinical integration theme in practice and the circumstances under which the Agency may or may not permit conduct that achieves clinical integration but that may lack financial integration.

**In re Greater Rochester IPA (2007)**

In the FTC’s Staff Advisory Opinion to Greater Rochester Independent Practice Association, Inc. (“GRIPA”), it is possible to see how clinical integration alone can alter the outcome. GRIPA sought to offer an entirely new health care product to consumers that involved collaborative clinical improvement programs designed to improve the quality of care and create efficiencies in the practice of medicine. GRIPA claimed that this new product of integrated services was “intertwined” with its proposed joint contracting with payers on behalf of GRIPA’s five-hundred independent and collectively bargain with payors).

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198 See **IMPROVING HEALTH CARE**, *supra* note 22, at 86-87, 118-19; Brooks et al., *supra* note 196.

199 See **STATEMENTS**, *supra* note 47 at 13, 36, 153. An additional inquiry in most antitrust investigations asks whether the arrangement at issue is likely to create market power and therefore violate antitrust law’s prohibitions against monopolies. *Id.* This inquiry, however, is beyond the scope of this article. *Id.*


201 See generally Letter from Markus H. Meier, *supra* note 54.

202 *Id.*

203 *Id.* at 8. Due to the recent trend of declining contracts and covered lives, GRIPA developed a program that integrated the services offered by physicians and clinical management activities “without employing a risk-sharing arrangement,” which is “designed to improve the quality of care and create efficiencies in the practice of medicine.” *Id.* at 3-4.
hospital-affiliated primary care physicians and specialists in forty separate areas, and the FTC agreed that the collective bargaining was reasonably necessary to achieve the likely efficiencies of the program.\textsuperscript{204}

The clinical integration component of GRIPA's proposed new product possessed several elements: (1) the development of a seamless, collaborative network of primary care physicians and specialists who all agree to refer patients to one another for care; (2) the 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 allow GRIPA physicians to share clinical information related to their common patients, order prescriptions and lab tests, and access patient information from hospitals throughout the community; (4) the expansion of care management services to more diseases and diagnoses; and (5) the appropriate calculation of savings attributable to the expected efficiencies.\textsuperscript{205}

In compliance with the revised 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 offered several justifications for the program's joint contracting aspect: (1) it created an easily identifiable network of providers and referring physicians; (2) it reinforced the internal referral system; (3) it ensured that all participating physicians were working towards the same financial goals; (4) it increased the opportunities for collaboration; and (5) it significantly reduced administrative costs and burdens.\textsuperscript{206} GRIPA also informed the FTC that its new product was “non-exclusive,” meaning that GRIPA physicians were free to negotiate with payers individually if GRIPA itself was unable to reach a joint agreement.\textsuperscript{207}

\textsuperscript{204} Letter from Markus H. Meier, \textit{supra} note 54, at 1. GRIPA anticipates roughly 90 percent of eligible primary care physicians and 75 percent of eligible specialists and sub-specialist physicians will participate in the program. \textit{Id.} at 4-5.

\textsuperscript{205} Letter from Markus H. Meier, \textit{supra} note 54, at 5. “One important aspect of the proposed program is that GRIPA physicians agree to refer patients to other GRIPA network physicians, except in unusual circumstances.” \textit{Id.} This will help patients continue to receive care under standard practices and allow GRIPA to maintain complete data pertaining to the patient's care. \textit{Id.}

\textsuperscript{206} See \textit{id.} at 18. “GRIPA believes that these benefits only can be fully achieved if its physicians all are contractually bound at the same time, through their acquiescence in the organization’s physician participation agreement, and through GRIPA’s joint contracts with payers.” Letter from Markus H. Meier, \textit{supra} note 54, at 18; \textit{see also} Brooks et al., \textit{supra} note 196.

\textsuperscript{207} See Letter from Markus H. Meier, \textit{supra} note 54, at 25.
The FTC ultimately agreed that GRIPA's new product of integrated services was sufficiently clinically integrated to justify the joint negotiation of price, thereby avoiding antitrust liability under a rule of reason analysis.\textsuperscript{208} Specifically, the FTC laid out several parts of the GRIPA arrangement that it found crucial to successful integration: a serious effort to encourage physician compliance through monitoring and potential expulsion from the program; participation by a broad spectrum of specialists and the system of referrals to physicians within the network; implementation of benchmarks to evaluate the quality of care; a high degree of investment by the physicians; and the necessity of integration to achieve efficiencies.\textsuperscript{209} Taken as a whole, the FTC determined that the GRIPA arrangement was not likely to discourage competition and informed GRIPA that it would not formally challenge the new product under federal antitrust law.\textsuperscript{210}

\textit{In re MedSouth (2002 and 2007)}

A similar result was reached in the FTC's two staff advisory opinion in \textit{MedSouth}.\textsuperscript{211} The original \textit{MedSouth} clinical integration opinion was issued in 2002.\textsuperscript{212} The follow-up opinion issued in 2007 drove home the point that an initial indication that the Agency will proceed under a rule of reason is by no means the same as an exemption, and that the FTC may circle back to explore whether the conduct of the entity is continuing to reflect the circumstances that initially led to the green light.\textsuperscript{213}

MedSouth proposed to create a new product through non-exclusive joint contracting and a web-based data system that allowed the participating physicians to share clinical information about their patients.\textsuperscript{214} MedSouth proposed to contract with

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\item \textsuperscript{208} See id. at 19. The anticompetitive aspects of the program are not crippling "if physicians’ participation in GRIPA in fact is non-exclusive" because it would not make sense for GRIPA to operate the program if the price agreement and collective negotiation arrangement would have little chance of succeeding in attaining higher prices for participating physicians. \textit{Id.} The payers could simply avoid contract with GRIPA for services. \textit{Id.} \textit{See also} Brooks et al., \textit{supra} note 196 (noting GRIPA charges more for some services and FTC found enhanced service may justify increase).
\item \textsuperscript{209} See Letter from Markus H. Meier, \textit{supra} note 54, at 16. The FTC particularly emphasized the substantial integration from the physician participants of the program, which could potentially lead to significant efficiencies in providing medical services. \textit{Id.}
\item \textsuperscript{210} See id. at 1.
\item \textsuperscript{211} See Letter from Jeffrey W. Brennan, \textit{supra} note 52.
\item \textsuperscript{212} See id.
\item \textsuperscript{213} See id. (stating the differences between a prospective advisory opinion and the actual of implementation of the program).
\item \textsuperscript{214} See id. The system allows doctors to share data on patient tests conducted at different times
\end{itemize}
payers on behalf of its member physicians on a fee-for-service basis for an integrated package of services, but as in GRIPA, membership was voluntary and physicians were still free to independently contract with payers and could join other physician contracting organizations as well.\textsuperscript{215}

In its 2002 letter, the FTC explained several elements of MedSouth’s clinical integration program that were relevant to its determination: (1) a requirement that its physicians comply with agreed-upon protocols; (2) the monitoring of such compliance; (3) a system to compare physician performance to established network benchmarks and required 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.\textsuperscript{216}

The 2002 approval noted two primary reasons why the proposed joint contracting element appeared to be reasonably necessary to achieve the program’s stated efficiency goals.\textsuperscript{217} First, the ultimate success of the new arrangement could not be attained if each physician individually contracted with the payers because there would be no guarantee of full participation by all the program’s members, since physicians could not be forced to individually contract.\textsuperscript{218} Second, the FTC found that the joint contracting arrangement 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.\textsuperscript{219} The FTC stated in its 2002 approval that the Agency would revisit MedSouth’s effect on competition and its success in achieving efficiencies at a later date.\textsuperscript{220}

The FTC ultimately made good on its promise and re-evaluated the MedSouth program for antitrust issues in 2007. Several concerns surfaced, and the second advisory letter focused on them: a loss of physician members; indications that physicians were in fact communicating with one another about the prices they would accept and other sensitive pricing issues (raising the \textit{Maricopa County} specter); evidence that physician and aggregate related data to show a particular trend. Letter from Jeffrey W. Brennan, \textit{supra} note 54. MedSouth anticipates that this system will reduce the number of duplicative procedures, speed up treatment and reduce medical errors. \textit{Id.}

\textsuperscript{215} See \textit{id.}

\textsuperscript{216} See \textit{id.} See also \textit{Simon, supra} note 182.

\textsuperscript{217} See \textit{Thomas B. Leary, The Antitrust Implications of "Clinical Integration:" An Analysis of FTC Staff’s Advisory Opinion to Medsouth, 47 ST. LOUIS U. L.J. 223, 233 (2003).}

\textsuperscript{218} See \textit{id.}

\textsuperscript{219} See \textit{id.}

\textsuperscript{220} See \textit{Letter from Jeffrey W. Brennan, supra} note 54.
practice oversight was less than rigorous; and a concern, indicated by MedSouth’s
difficulty in securing payer contracts, that patients and payers did not recognize the
clinical integration features of the arrangement as something worth paying for as better
than just individual physician services alone.\textsuperscript{221} Notwithstanding these notable
deficiencies, the FTC reaffirmed its approval of the joint contracting element of the
MedSouth program as reasonably necessary to achieve the projected efficiencies of the
arrangement.\textsuperscript{222}

In re \textit{Suburban Health Organization}

Yet another example of the FTC approach is the opinion in \textit{Suburban Health
Organization, Inc.}, (“SHO”).\textsuperscript{223} SHO offers an example of a clinical integration program
that did not pass muster.\textsuperscript{224} SHO was a program of partial integration among several
hospitals and their primary care physicians. The joint contracting element of the
arrangement involved SHO as the negotiator of primary care payment rates for its
physicians’ services. SHO represented the exclusive means through which payers could
gain access to these 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 of five
percent of their compensation for meeting quality management targets.\textsuperscript{225}

\textsuperscript{221} \textit{See id. } \textit{See also Simon, supra note 182.}
\textsuperscript{222} \textit{See Letter from Jeffrey W. Brennan, supra note 54.}
\textsuperscript{223} \textit{See generally Letter from David R. Pender, supra note 200.} The FTC concluded that the
program’s efficiencies do not sufficiently override the competitive restraints. \textit{Id.} at 13.
Accordingly, the FTC concluded the price agreements and exclusivity requirement components
of the program would unnecessarily restrain competition. \textit{Id.}
\textsuperscript{224} \textit{See id.} While the FTC noted SHO’s proposed program had the potential to improve the
quality and efficiency of treating certain medical conditions, SHO’s lack of enforcement
mechanisms and the program’s inclusion only of hospital-employed primary care physicians were
some of the many significant limitations on the program. Letter from David R. Pender, \textit{supra}
note 200, at 4-6.
\textsuperscript{225} \textit{See id.} at 2-3. SHO’s program intended to include educational programs to educate patients,
prevent diseases and encourage healthy lifestyles. \textit{Id.} at 3. The program would also manage
patient cases, such as diabetes and asthma, to further reduce the incidence of avoidable medical
interventions and their associated costs. \textit{Id.} In addition, the program would develop web-based
technology to monitor and track the data. Letter from David R. Pender, \textit{supra} note 200, at 3.
Through these mechanisms, SHO sought to improve the efficiency and quality of care provided
The FTC rejected SHO's clinical integration program, stating that the joint contracting by physicians was not reasonably necessary to achieve the efficiencies that the program was intended to produce. Several deficiencies were noteworthy, including the structure of the integrated entity, which included several hospitals whose services appeared redundant, an excessive reliance on hospitals to oversee the performance and payment functions for the physician services, little evidence of true clinical integration as shown through physician interdependence, inadequate effort to tackle major health conditions that account for significant costs, and an inability to demonstrate how the entity would achieve interaction between its primary care physicians and non-participating specialists. In essence, SHO boiled down to a group of hospitals that attempted to control access to and the price of primary care services in the market, without evidence that the market would gain from new clinical efficiencies as a result. 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."
In re TriState Health Partners, Inc. (2009)

In its most recent advisory opinion on the topic of clinical integration among providers, the FTC approved TriState’s program and concluded that the joint contracting by physicians was justified. TriState is a physician-hospital organization that includes a hospital and 212 physicians, both primary care and specialists, and its 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.”

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.

To justify its collective bargaining of price, TriState described several specific aspects of its clinical integration program: (1) physicians must participate in all medical
management programs, serve on committees when needed, and share best practice ideas and methods; (2) physicians must refer patients to network providers when medically appropriate; (3) the 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.  

The advisory letter set forth several factors the FTC will consider when analyzing whether the proposed integration has a likelihood of achieving significant efficiencies. First, the Commission will analyze whether the proposed program is selective in choosing network physicians who are likely to further the program’s efficiency objectives. Meier noted that while TriState is not initially selective (any physician can join), there did exist a number of imposing requirements that would effectively discourage those not fully committed. Second, the Agency will consider whether the participating physicians are investing both monetary and human capital into the program. Here, the FTC determined that while the $2,500 entry fee was too low

234 See id. at 8-9 (detailing requirements a physician must comply with in order to participate in proposed program and mechanisms in place to assure compliance). The advisory opinion noted, however, that TriState is still determining how performance will be measured, and thus the FTC was unable to discuss the specifics of how the evaluation process will function. Id. at 9. 

235 See Letter to Christi J. Braun, supra note 54, at 15 (discussing how such integration can be demonstrated). Integration can be established by implementing a program to evaluate and modify practice patterns of the participating physicians in order to increase cooperation and interdependence, ensure quality and also to control costs. Id. See also Johnson & Greer, supra note 230. 

236 See Letter to Christi J. Braun, supra note 54, at 16. The participating physicians must agree to certain constraints, as well as certain oversight and remedial activities. Id. A tension may result, however, from the program’s desire to include all eligible physicians and between their need to select only the providers that are willing to accept these business constraints as the program attempts to further its goals of controlling costs and improving the quality of care. Id. 

237 See id. The two most important requirements of participation are that each physician must become a full member of TriState and execute a participating provider contract. Letter to Christi J. Braun, supra note 54, at 17. Physicians will need to assess their willingness to adhere to the set-out requirements. Id. The end result will be the inclusion of only those physicians who have fully committed to the organization and proposed program, and in turn, will result in a limited provider panel. Id. 

238 See id. at 17-19 (outlining “Physician Investment of Monetary and Human Capital into
to "strongly motivate" physicians to work towards the success of the program, the "sweat equity" in terms of time and effort did evidence a substantial degree of commitment to the program.\textsuperscript{239} Third, the FTC will look at the structural and operational elements of the program to determine whether they are likely to foster significantly increased interaction among the participating physicians in the treatment of patients.\textsuperscript{240} Meier stated the FTC's view that adequate physician interaction could be expected in the TriState program through the use of clinical practice guidelines, evidence-based standards, the in-network referral policy, the use of HIT, the collection and use of performance data, the requirement that all physicians participate in all aspects of the program, and the robust feedback mechanisms.\textsuperscript{241} Fourth, the Commission will want to see evidence regarding how the program will be evaluated over time.\textsuperscript{242} Although this element appeared to be lacking in TriState's program, Meier recognized the past successes of similar pilot programs as predictive.\textsuperscript{243} Finally, the FTC will consider whether the participation of a hospital will create an inherent conflict in terms of the hospital's need to fill beds.\textsuperscript{244} The FTC determined under the facts presented, and because of Maryland's unique rate regulatory system, that the hospital did not have

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Proposed Program'').
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\textsuperscript{239} See Letter to Christi J. Braun, supra note 54, at 18-19. Meier stated that the $2,500 entry fee along with money spent purchasing a new computer and related equipment along with lost billing time spent on training was simply not enough of a financial investment in the program to give physicians a stake in its overall success. \textit{Id.} at 18. Meier did, however, acknowledge the agency's opinion that the investment of time and energy in various committees, collaborating in patient care, and implementing new guidelines would combine with the moderate financial investment to sufficiently indebt physicians to the program's success. \textit{Id.} at 18-19.

\textsuperscript{240} See id. at 19-20 (discussing "Infrastructure and Program Capability of Program" regarding "Integrating the Provision of Care and Achieving Efficiencies").

\textsuperscript{241} See Letter to Christi J. Braun, supra note 54, at 18-19. The letter does lay out a concern over the "leakage" of patients to other non-TriState providers if allowed to seek care out of the network by an employer or other payer. \textit{Id.} at 20. The agency is concerned with the possible creation of gaps in the information available to TriState about a patient's treatment and health status. \textit{Id.} Meier concluded that this was a valid concern about the program and that the effectiveness of proposed remedies could not be ascertained at the time of writing. \textit{Id.}

\textsuperscript{242} See Letter to Christi J. Braun, supra note 54, at 20-21 (analyzing "Measurement and Evaluation of Performance Results").

\textsuperscript{243} See id. The proposed program will compare individual and group performance peer, regional, and national benchmarks but does not define by what measurements. \textit{Id.} at 20. TriState did not detail how it will measure the proposed program on a more macro level such as in terms of cost or utilization of services by covered populations either. \textit{Id.} at 20-21. Meier stated, however, that the FTC had confidence in TriState's pilot program for diabetes treatment and considered it an indication of the proposed program's eventual success. See Letter to Christi J. Braun, supra note 54, at 21.

\textsuperscript{244} See id. at 21-22 (analyzing "Effect of Washington County Hospital Association's Involvement on the Proposed Program's Ability and Likelihood of Achieving Significant Efficiencies").
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.

Because in the overall analysis the FTC found that TriState's program was likely to produce its claimed efficiencies, the FTC next 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 pointed out several reasons why: the success of the program heavily depended on all physicians participating in all contracts under the same criteria and protocols; joint contracting would reinforce the in-network referral policy thereby maximizing effectiveness; more payer contracts would spur the willingness of the providers to invest time and energy in the success of the program; certain scale economies existed; the branding of a single entity would enhance business operations; and administration overhead would be reduced. Taken together, these reasons justified the joint contracting as subordinate and ancillary, but reasonably necessary, to TriState's efforts to improve efficiency and quality in the provision of medical care to patients. Therefore, the FTC staff opined that this arrangement did not run afoul of antitrust law's prohibition against price-fixing.

The FTC will clearly take a hard look at the claimed efficiencies of clinical integration and the resulting necessity of joint physician contracting to achieve those

245 See id. at 22. The hospital has an economic incentive to continue incremental admission of patients, but does not seem to the FTC to have an incentive to offer excessive services or lengths of stay beyond the reimbursement rate of discharge set by the state. Id.

246 See Letter to Christi J. Braun, supra note 54, at 22. Any financial incentive by the hospital to increase admissions may be offset by the Washington County Health System's incentive to rationalize and more efficiently provide health care services. Id.

247 See id. at 23. More specifically, the FTC believes that efficiencies in both cost and quality will result from the incorporation of evidence-based best-practices in medicine, as well as the inclusion of increased "reporting, observation, oversight, review, and evaluation." Id.


249 See Letter to Christi J. Braun, supra note 54, at 36-37.

250 See Letter from Michael D. Maves, Executive Vice President and CEO, American Medical Association, to Jon Leibowitz, Chairman, F.T.C. 1 (May 13, 2009) (seeking to confirm FTC's decision that joint contract arrangements amongst a non-exclusive physician network will not be subject to price-fixing violations), available at http://www.ftc.gov/os/comments/bouldervalley%20ipa/090514ama.pdf; Letter to Christi J. Braun, supra note 54, at 36-37 (concluding that the pro-competitive effects would not conflict with antitrust prohibitions).
efficiencies. The Agency has indicated that in such arrangements it will focus on substance, not form, to determine the likelihood of a network producing these significant efficiencies. Based on the FTC opinions and agency guidelines, several elements for a successful clinical integration program are clear. There must be evidence of actual interdependence among physicians in the provision of care to patients that includes true collaboration and the sharing of information. This is the key, and without significant indicia of provider collaboration, proposed clinical integration programs will fail. In the same vein, successful programs must require significant physician investment of both monetary and human capital, and an agreement to comply with the benchmarks, standards, and protocols put in place by the network with corresponding consequences for non-compliance by physicians.

A successful clinical integration program must also include both primary care physicians and specialists that are required to refer patients in-network, and treat those patients by following established clinical practice guidelines for a broad spectrum of diseases and disorders. Health information technology systems must be in place to allow physicians to efficiently exchange patient information and information on best practices, and for the gathering, analysis, and communication of utilization and claims information to improve quality and reduce cost. These information technology systems must also have the capability to track and measure physician compliance and performance in accordance with physician-authored benchmarks and standards.

Once these elements are established, the FTC opinions reviewed above also establish several factors to determine whether joint physician contracting as part of a clinically integrated program is legal under federal antitrust law, i.e., reasonably necessary to achieve the program’s claimed efficiencies. First, the joint contracting should be

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251 See Harbour, supra note 56, at 3.
252 See id. Harbour states that for organizations which clear the minimal hurdle of ‘inherently suspect,’ the FTC’s analysis needs to move further to evaluate whether integration will yield the expected efficiencies. Id. at 6.
253 See U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE: STATEMENT 9: ENFORCEMENT POLICY ON MULTIPROVIDER NETWORKS, available at http://www.ftc.gov/bc/healthcare/industryguide/policy/statement9.htm (last visited Nov. 12, 2009) [hereinafter STATEMENT 9]. In searching for true interdependence of physicians, the FTC believes this is the cornerstone marker that leads to efficiency yields throughout the system. Id.
254 Id.
255 Id. Possible consequences for non-compliance include remedial punishments and/or exclusion from the network. Id.
256 See Simon, supra note 182.
257 See infra notes 287-288 and accompanying text.
non-exclusive, thus allowing physicians to individually contract when the network and
payers cannot agree to terms. Second, the joint contracting should not involve the
unnecessary exchange of price information among physicians and hospitals. And
third, the price setting should be only for those services that are part of the clinical
integration program.

Revised Statement 8, supplemented by these advisory opinions, thus provides a
blueprint for what adequate clinical integration should contain. Such programs
require, by definition, that the participating physicians clinically integrate their practices
through interdependence upon one another for the continuum of care provided. When such conduct is evident, as well as an ambitious quality improvement plan, real
oversight, and use of clinical and performance information, joint contracting essentially
flows of necessity, since as the FTC pointed out in MedSouth, it is impossible to achieve
these improvements in the absence of joint contracting. Also essential is evidence of
the value received by payers and patients, i.e., that payers and patients believe that the
investment is solid and that value is being received. This belief could come in the
form of the contracts actually held or under negotiation, and the development of
performance results not only for the IPA or practice group but for the payers and
patients.

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258 See STATEMENT 9, supra note 253 (examining Frederick County’s efforts at individualized contracting and finding that too few enrollees are involved to justify its efforts).

259 See id. Agreed upon fee schedules help providers achieve a higher level of efficiency because it does away with unnecessary communication between hospitals and physicians when prices are pre-determined ahead of time. Id.

260 See id.

261 See STATEMENT 8, supra note 166. Adequate clinical integration programs exist within a “safety zone” where their actions do not raise substantial competitive concerns, and, therefore will not be challenged by agencies under Antitrust laws. Id.

262 Id. Physicians have the advantage of financial interdependence when they participate in a joint venture, in addition to possible cost savings, “cost controls, case management and quality assurance, economies of scale, and reduced administrative or transaction costs.” Id.

263 U.S. DEPT OF JUSTICE & FED. TRADE COMM’N, ADVISORY OPINION FOR MEDSOUTH, Feb. 21, 2002, available at http://www.ftc.gov/opa/2002/02/medsouth.shtm. The opinion specifically points to the cost efficiencies and reductions passed to the consumers while integrating medical services in a manner to create high quality with fewer errors. Id.

264 See id. Two reasons for MedSouth’s positive review in the above-ruling were fewer medical misdiagnoses and the ability for patients to purchase services directly from the health care provider and not exclusively from the network. Id.

265 See id. Network doctors still need to negotiate contracts with the major health plans and the amount of physicians represented could impact the negotiated price, which in turn would impact the savings to the network. Id.
V. Accountable Care Organizations: A Path to Clinical Integration?

Critical to any health reform effort will not only be the expansion of health insurance to cover all U.S. individuals but also making such coverage affordable in light of the fragmentation and variation in the delivery of health care services as discussed above. In 2008, Shortell and Casalino proposed the concept of “Accountable Care Systems” for the re-design of the delivery system aimed at aligning cost with the value of care received, in which a health care entity implements “organized processes for improving the quality and controlling the costs of care and be held accountable for the results.”266 This idea closely parallels clinical integration and has recently revived the discussion of provider integration as a critical element to improve quality and lower costs.267 Indeed, during the 2009 health reform debate, much attention has been paid to the concept of Accountable Care Organizations (“ACOs”).268 Upon first impression, the notion of ACOs seems like just another addition to the “alphabet soup”269 of physician joint ventures seeking to join forces in order to leverage bargaining power with health insurance companies. There are, however, valid reasons why this model of health care delivery is gaining traction in the current debate on national health reform.270

In keeping with earlier FTC pronouncements about clinical integration, an ACO can be defined as an integrated health care delivery system that relies on a specific

266 See Shortell & Casalino, supra note 35.
267 See Asyltene, supra note 176 (explaining that clinical efficiencies can be achieved with greater ease when physicians and hospitals work together).
268 See Accountable Care Promotion Act of 2009, H.R. 2959, 111th Cong. (2009) (detailing goal to create a pilot program to reduce the growth of healthcare expenditures). These goals include promoting accountability, investing in infrastructure for more efficient service, and rewarding efficient physician practices. See also H.R. 3200, 111th Cong. Division B, Title III, §§ 1301 et seq. (2009), (amending Social Security Act § 1866D(a)(1)-(3) with objective of creating affordable healthcare and reducing healthcare spending).
269 See Danzis, supra note 48, at 541 (discussing “alphabet soup” risen from physicians resisting large organizations while desiring greater leverage that they afford). Physicians have thus created joint ventures in order to gain such leverage. Id.
270 See H.R. 2959 § 2 (a)(2) (calling for more efficient services); see also Elliott S. Fisher et al., Fostering Accountable Health Care: Moving Forward in Medicare, 2 HEALTH AFF. 28, 219-231 (2009) (noting the lack of accountability for costs and quality of care); Elliott S. Fisher et al., Creating Accountable Care Organizations: The Extended Hospital Medical Staff, 1 HEALTH AFF. 26, 44-57 (2006) (noting serious amounts of waste resulting from inefficient health care system). The authors note that by utilizing the extended hospital medical staff, i.e. focusing in on the referral systems of physicians, this could create a network by which to create greater accountability and monitor performance. Id. See also Brookings Inst. & The Dartmouth Inst. for Health Pol’y and Clinical Prac., Issue Brief: Accountable Care Organizations (Mar. 2009) (noting the need for payment reform and use of the ACO model).
network of primary care physicians, specialists, and hospitals to provide care to a defined population of patients. The ACO would establish a spending benchmark based on the expected spending for a given condition. The defined network would be responsible for the quality of care delivered to patients, and if the ACO improves quality while slowing spending growth, it would receive shared savings from the payer. Conversely, the network would be penalized for delivering low-quality, high-cost care.

Based on these criteria, The Medicare Payment Advisory Commission (MedPAC) recommended the establishment of ACOs within Medicare in its 2009 Report to Congress. These recommendations were incorporated into proposed health reform legislation, America’s Affordable Health Choices Act of 2009, as a demonstration provision creating a pilot program to test ACOs as a new and formally recognized class of Medicare provider.

The basic purpose of an ACO parallels that for clinically integrated models of care delivery as articulated in the Statements: to encourage a significant advance in health care quality and efficiency through organizational structure and operational change by organizing physicians and hospitals into more efficient fee-for-service delivery arrangements. The ACO demonstration provisions contained in the House of Representatives’ “Tri-Committee” health care reform legislation under consideration in

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271 See H.R. 2959 § 2(b)(1)(A-B) (explaining the definition of an Accountable Care Organization and its requirements). An Accountable Care Organization is a group of physicians organized for the purpose of physicians’ services. Id. Requirements include a legal structure to distribute incentive payments, a sufficient number of primary care physicians for applicable beneficiaries, groups consisting of only participating physicians, group reports on quality and frequency, groups contributing to a “best practices” network, websites to improve efficiency and to share effective methods and using patient-centered care processes. Id.

272 Id. at § 2(c)(1)(D) (describing incentive payments as well as penalties). ACOs are to participate in a partial caption model governed by the Secretary, who maintains the discretion to alter the model. Id.


276 Id. at Division B, Title III, §§ 1301-1303 (amending Social Security Act, 42 U.S.C. § 1866D(a)(1)-(3) (2006)).

277 See Report to Congress, supra note 274, at 39 (outlining central goal of implementing ACOs).
the summer of 2009\textsuperscript{278} add further detail, establishing ACOs in Medicare to promote accountability for a patient population, "encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery," and "reward physician practices and other physician organizational models for the provision of high quality and efficient health care services."\textsuperscript{279}

However as a whole, the ACO provisions in H.R. 3200 focus much more heavily on payment, with efficiencies in payment methodology identified as their central purpose.\textsuperscript{280} The provisions include only limited indicia of clinical integration and offer none of the rich detail on quality and efficiency indicators set forth in the \textit{Statements} and described in the subsequent FTC advisory opinions:

(2) QUALIFYING CRITERIA- The following are criteria described in this paragraph for an organized group of physicians to be a qualifying ACO:

(A) The group has a legal structure that would allow the group to receive and distribute incentive payments under this section.

(B) The group includes a sufficient number of primary care physicians for the applicable beneficiaries for whose care the group is accountable (as determined by the Secretary).

(C) The group reports on quality measures in such form, manner, and frequency as specified by the Secretary (which may be for the group, for providers of services and suppliers, or both).

(D) The group reports to the Secretary (in a form, manner and frequency as specified by the Secretary) such data as the Secretary determines appropriate to monitor and evaluate the pilot program.

(E) The group provides notice to applicable beneficiaries regarding the pilot program (as determined appropriate by the Secretary).


\textsuperscript{279} See id.

\textsuperscript{280} See id. at Division B, Title I, §§ 1143-1147 (discussing the idea of analyzing payment methodologies used in different plans for applicability to Medicare).
(F) The group contributes to a best practices network or website, that shall be maintained by the Secretary for the purpose of sharing strategies on quality improvement, care coordination, and efficiency that the groups believe are effective.

(G) The group utilizes patient-centered processes of care, including those that emphasize patient and caregiver involvement in planning and monitoring of ongoing care management plan.

(H) The group meets other criteria determined to be appropriate by the Secretary.281

Nothing in the description of an ACO would require all-payer performance reporting at both the individual physician and aggregate system-wide levels, although reporting to Medicare appears to be contemplated.282 Furthermore, no provision would explicitly require the use of enforceable quality measurement tools applicable to individual members or the use of technology to support improvements in patient care through information sharing and practice support.283 There appears to be no Congressional intent in these ACO provisions to test both payment innovations and integrative clinical innovation of the type that not only justifies but indeed necessitates joint approaches to the negotiation of payment. In short, the ACO provisions in H.R. 3200 are quite paradoxical. Despite the clear presence of clinical integration in federal public policy and its heightened attention as essential to quality and safety, the demonstration provisions stress the restructuring of payment rather than the restructuring of health care delivery itself.284 It would seem logical to combine these two goals to justify, automatically, an antitrust exemption from a per se price fixing charge for any entity that is certified as an ACO. In doing so, the conditions that favor efficiency from an antitrust law perspective and those that favor efficiency from a health care delivery perspective would be able to reinforce one another. Because the Congressional expectations for ACO quality and efficiency performance are limited in number (the legislation merely sanctions a handful of demonstrations) and are limited in scope when compared to explicit federal antitrust policy on clinical integration, the ACO provisions as embodied in the House bill represent not so much a decisive breakthrough as a potential loss of an opportunity for the decisive use of federal policy further clarification

281 See id. at Division B, Title III, §§ 1301-1303 (amending Social Security Act § 1866D(a)(1)-(3)).
282 See H.R. 3200.
283 See id.
284 See supra note 43 and accompanying text (discussing American Recovery and Reinvestment Act funding for HIT).
and advancement of clinical integration as a model of care delivery.285

Because the model is voluntary and constrained, the legislation essentially segregates health care providers that elect to pursue change from the many more that continue to practice under the status quo, albeit under increasingly difficult circumstances.286 Medicare, the health care financing system that, from a historic vantage point, has driven widespread change among all payers, fundamentally asks no system-wide changes of providers in the near future.287 It is possible that existing entities that meet (or are willing to realign themselves to meet) the ACO definition would seek certification, but it is unclear what inducements would be needed or available to cause new ACOs to spring up.288 As noted, current market trends showing a significant decline in financially integrated entities as compared to the 1990s support the argument that today's physicians and hospitals as a group remain interested in the entrepreneurial elements of health care delivery through use of high-technology procedures, physician-owned hospital arrangements, and maintaining a high volume of services.289 Inevitably this has led to an increase in direct competition between physicians and hospitals (but notably without the reduction in price that such competition is supposed to produce) and therefore a growing unwillingness to cooperate or integrate (recent uptake in clinical integration notwithstanding). Reversing these trends will be difficult; therefore measuring the outcomes of existing ACO-like pilot programs290 is critical if we want to convince providers that this type of collaboration

285 Compare infra notes 292-96 (discussing absence of mandates in ACO provision for use of HIT or other quality enhancing measures), with supra notes 165-69 (setting forth elements of successful integration based on FTC advisory opinions).

286 See Asyltene, supra note 176, at 7-9 (discussing incentives for providers to participate in ACO and shifts in case management methods); see also Jack Lewin, Ready to Reduce Readmissions, THE LEWIN REPORT, (Oct. 20, 2009), http://lewinreport.acc.org/?tag=/readmissions (discussing need for alternative ACO models for organizations unable to easily meet provisions' incentive criteria).

287 See Robinson & Ginsburg, supra note 27.

288 See Asyltene, supra note 176, at 3 (noting minimal requirements for ACO certification). But see REPORT TO THE CONGRESS, supra note 274, at 47 (discussing possible reductions in FFS rates for non-participating providers to create incentives to participate).


will increase, not decrease, their bottom line.291

Finally, several practical barriers to the successful development of ACOs exist. For the model to work, highly-charged political decisions will have to be made, particularly with respect to changes in the payment system. The selection of measures, the establishment of data collection and auditing procedures, and how and for what level of improvement will payments be made and at what amounts are all still unanswered but critical to the success of any ACO or clinical integration program.292 Most fundamentally, of course, is the question of whether to introduce new constraints on payments that essentially restrict participation and payment to individuals and entities that have achieved integration through the use of affiliations, HIT adoption, and the use of collaborative practices that change the way medicine is practiced and that carry consequences for collaboration members whose conduct falls short of the mark.

In summary, the current interest in ACOs offers an important opportunity to create a new generation of entities that can gain recognition as qualified to engage in joint contracting practices with all payers free and clear from antitrust scrutiny. The introduction of the concept of ACOs into Medicare could advance and reinforce the goal of system-wide efficiency envisioned in the Statements were Medicare to consider such a shift in practice as a condition precedent to payment and if ACO certification were to expand to include all of the factors that the Agencies have identified as essential to clinical integration.293 At this point, the reform of Medicare payment law, coupled with an active effort to merge these principles with the strong clinical integration provisions found in the Statements of Antitrust Principles in turn would represent the types of legal incentives that could foster the “bottoms-up” approach to change that is vital to achieving a broad shift in the culture of medicine.294

291 See Tompkins, supra note 132.  
293 Compare supra notes 147-59, 165-75 (discussing Statements 4, 5, 6, and 8) with notes 274-79 (analyzing demonstration requirements).  
294 See Francis J. Crosson, Medicare: The Place To Start Health System Delivery Reform, 28 HEALTH AFF. 2, w232-33 (2009) (emphasizing need for Medicare to drive change and the need for incorporation of antitrust into debate about payment reform).
VI. Conclusion

The American health care system is at a crossroads. It is possible that the coming years will see the gradual introduction of a near-universal health insurance framework that assures at least a floor of health care financing for the vast majority of Americans. It remains to be seen whether this vast infusion of financing (the CBO estimates new investments in public insurance expansions and new private health insurance subsidies of between $800 billion and $1.3 trillion over ten years depending on the legislative proposal under consideration) will in turn generate the types of underlying system reforms that are crucial to clinical integration, quality, and efficiency.\(^{295}\) In this regard, two sources of law become critical. The first is the terms of payment that will drive these new or expanded financing arrangements. To date, Congress has shown a willingness to incentivize the adoption of HIT but to take only small steps in tying provider participation in public insurance to adoption of the indicia of clinical integration. The ACO demonstrations are a step in the right direction, but the size of the step is mighty small. Other public and private insurers could of course be more aggressive, conditioning provider participation in public and private employer sponsored plans or Medicaid on a decisive shift into clinical integration. But to the extent that Medicare historically has served as the guide-star for health system change, the concern is that other payers will essentially adopt a wait and see attitude, tolerating very slow change while Medicare slowly evolves. Certainly the introduction of payment incentives may help, but as recent evaluations of pay for performance initiatives show, at an individual payer level, the numbers of physicians, hospitals, and patients affected, as well as the amount of dollars in play, typically are much too small to generate the large-scale shift in culture that is so obviously needed now.\(^{296}\)

This then suggests the need for a supply side strategy as well. The Statements and guidelines provide the clearest evidence to date of what is meant by a true clinical integration, with or without financial integration. Several specific applications of these statements have been notable, including both positive advisory opinion letters, as well as


\(^{296}\) See Robinson & Ginsburg, supra note 27, at 277 (describing payment incentives); see also Crosson, supra note 294, at 233 (noting that because the demand specialists generate is greater than incentives, the demonstration might provide large-scale market competition required to induce participation).
the elements of settlements in a series of high profile civil prosecutions. These actions alone, while illuminating, may do little to foster change since these cases are one-of-a-kind encounters, initiated either by a single entity that desires to pursue change or by a single prosecution that, no matter how highly publicized, remains just that.

The question becomes whether it is time to move more aggressively on the supply side through the establishment of certain types clear antitrust exemptions, as opposed to simply signaling perhaps the more tolerant approach toward ongoing agency oversight of conduct represented in the individual rule of reason advisory opinions and analyses. With a more robust exemption comes the potential for a legal incentive that could induce more widespread action. The existence of an exemption of course does not mean an end to ongoing oversight. It is entirely possible that an exempt entity could fall off the wagon at some point and that corrective action would be needed. At the same time, an exemption takes on a level of power that goes beyond a kind and gentle review and may signify a sufficient level of shift in agency outlook to spur further provider action.

Today antitrust exemptions exist for certain types of conduct such as full financial integration. We believe that the time has come to take the matter a step further in two situations. The first is to craft an outright exemption for joint conduct that involves the sharing of quality, efficiency, practice, and patient outcome information across a geographic area but that lacks any of the indicia of price-setting. The Statements clearly do not proscribe such efforts, but they do not come right out and encourage them either. A fair amount of legal digging is necessary in order to find the thread of legality. A guideline expressly geared to geographic information sharing involving both payers and providers, and the conditions under which such information sharing will be considered lawful, might conceivably broaden the communities in which competitors agree to join together to critically self-examine conduct on a market-wide basis. This exemption, particularly if tied to community grants to support such efforts, appears to be an important step forward.

The second area that we believe justifies more decisive agency intervention in the form of a true exemption involves clinical integration. Providers need to know more than the fact that their activities will be scrutinized under a gentler standard of review. They need to be aggressively encouraged to come together into entities that function as one, even if comprised of disparate economic interests and lacking the indicia of full financial integration. The quest for full financial integration ultimately might bear fruit,

297 See Asyltene, supra note 176 (discussing Statements' application).
but it is our theory that extinguishing the world of independent small health care businesses is a generational undertaking. In the meantime, aggressive pursuit of the clinical integration pathway in the form of a clearer exemption could yield multiple confederations of physicians and hospitals willing to act as one in the management of multiple serious and chronic conditions, willing to adopt HIT, willing to collaborate in the use of common practice guidelines, a common performance reporting system, and a common approach to the enforcement of performance. The reward of course is the ability to engage in joint economic negotiations which becomes a necessary adjunct to quality and efficiency improvements. Added to this mix of conduct already identified by the enforcement agencies, a clearer clinical integration exemption might also be fashioned that encompasses a requirement that the confederation be willing, for one or more conditions, to test case and episode of care payment mechanisms that, even if not built on principles of full financial risk, nonetheless depend for their success on close collaboration across confederation members in order to realize economic gain.298

It is our view that the time has come for an updating of the Statements of Antitrust Enforcement Policy in Health Care to provide a specific safety-zone that explains the types of permitted information sharing activities related to health care quality and efficiency that will be permitted, that is written to capture geographic regions so as to be multi-payer and multi-provider, and that spells out the conditions under which such a safety-zone will be available. The safety-zone needs to clearly delineate what such entities can and cannot do in the exchange of data beyond merely producing data for isolated use by individual payers and providers. For example, might such entities be empowered to actually convene health care buyers and sellers to actively engage in value-based purchasing, that is, to understand and act on pricing variation in relation to quality, to test new mechanisms for paying for health care, or to share information about the results?

We also recommend a specific safety-zone under Statement 8 that would be applicable to clinical integration. This clinical integration safety-zone should explain what level of integration is sufficient to justify collective price negotiations, and when and how such joint negotiations can be lawfully undertaken. The considerations should be expanded to include the testing of at least one payment model that is built on financial integration as reflected in case payments or episodes of care and that is tied to at least one high cost chronic condition. The safety-zone in short should address how the agencies will view a clinical structure that contains some degree of both financial and clinical integration, but does not quite meet the threshold for establishing either under

298 See de Brantes et al., supra note 7, at 1033-36 (describing Prometheus payment model).
current antitrust law. This safety-zone, in turn, should inform the Secretary of HHS in the implementation of health reform's ACO provisions, so that any entity certified as an ACO will, even if not fully financially integrated, be deemed sufficiently clinically integrated to permit cross-payer negotiations over pricing. Any ACO reform provisions must include the same indicia of clinical integration found in the Statements and not be solely focused on payment methodology reform.

With these steps, we believe that federal antitrust law will have begun to move more decisively toward encouraging the types of system behaviors that payers and patients need at this point. No single legal tool can get the job done. It is politically impossible to super-impose broad payment reforms on an underlying health care system that is politically bent on resistance to a fundamental realignment of interests. At the same time, it is not possible to realign the underlying system of care in the absence of clear signals from payers that they will meet this realignment with major changes in payment structure that encourage basic reforms in practice. Where health care is concerned, two bodies of law—those that push and those that pull—need to work together to make change happen.