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Via E-mail and Federal Express

Mr. Donald S. Clark
Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, D.C. 20580

Dear Mr. Clark:

The Section of Antitrust Law is pleased to submit the attached comments in response to the Federal Trade Commission's ("FTC") public workshop on Health Care and Competition Law and Policy.

The views expressed herein are being presented on behalf of the Section. They have not been approved by the House of Delegates or the Board of Governors of the American Bar Association and, accordingly, should not be construed as representing the policy of the Association.

If you have any questions after reviewing this report, we would be happy to provide further comments.

Sincerely,

Robert T. Joseph
Chair, Section of Antitrust Law

Enclosure

COMMENTS REGARDING THE FEDERAL TRADE COMMISSION'S WORKSHOP ON HEALTH CARE AND COMPETITION LAW AND POLICY

Section of Antitrust Law
American Bar Association
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I. INTRODUCTION

On September 9 and 10, 2002, the Federal Trade Commission ("the Commission") conducted a workshop on competition law and policy for health care financing and delivery ("the Workshop"), which considered the impact of competition law and policy on the cost, quality and availability of health care, and the incentives for innovation in the field. This initiative is part of a broader examination by the Commission of antitrust enforcement and policy in the health care industry.

The Section of Antitrust Law of the American Bar Association (the "Section") applauds the Commission for conducting the Workshop as a means of affording the various constituencies in the health care industry the opportunity to discuss important competition issues with the Agencies. The Section welcomes the opportunity to submit these comments on competition policy and antitrust enforcement as it is evolving in the health care field. These comments are submitted with a view toward once again emphasizing the importance of competition and appropriate antitrust enforcement in the health care industry; addressing some of the specific topics that were covered at the Workshop in September, including clinical integration, quality of care and group purchasing organizations; and identifying subjects or questions that the Section believes are worthy of more extensive consideration by the Commission in the future.

These views are presented only on behalf of the Section. They have not been approved by the House of Delegates or the Board of Governors of the American Bar Association ("ABA"), and should not be construed as representing the position of the ABA.

II. ROLE OF COMPETITION AND ANTITRUST ENFORCEMENT IN HEALTH CARE IN PROMOTING EFFICIENCY AND CONSUMER WELFARE

A. The Critical Importance of Competition

Health care markets have experienced rapid and far-reaching changes in recent years. These markets, which are primarily local in nature, vary widely in the number, size and quality of payors and provider organizations, as well as in prices and price trends. Notwithstanding these differences, competition among payors and health plans, and among providers and provider networks, has been an important force in enhancing consumer welfare by promoting the most efficient allocation of resources so as to offer consumers competitively-priced, high-quality and accessible health care goods and services. Antitrust enforcement has been an essential support for the success of such competition, given the law's basic objective of encouraging and protecting the competitive process by inhibiting practices that unreasonably interfere with free competition.

Antitrust enforcement has, for example, thwarted the efforts of some health care industry participants to insulate themselves from competition or to exclude alternative providers from offering services to consumers. Antitrust enforcement has been largely responsible for preventing or ending practices that restrict competition and for opening markets to new and innovative forms of health care, such as HMOs and PPOs.

In recognition of the critical importance of such competition, courts and federal and state antitrust enforcement authorities have interpreted the antitrust laws as fostering two fundamental objectives: (1) to invalidate anticompetitive arrangements; and (2) to afford needed flexibility for arrangements in a dynamically changing industry that

enhance efficiency and consumer welfare, and address issues of overcapacity, health care quality and utilization. The analytical principles embodied in antitrust law have evolved through numerous applications across a broad array of markets and conduct, including a number of the specific areas identified in the Workshop.

B. The Antitrust Laws Permit Legitimate Joint Conduct and Joint Contracting

Health care professionals have engaged in varying degrees of consolidation in response to market forces in recent years. Some have engaged in direct mergers to form large practice groups, either independently or as a part of health systems which include hospitals and other providers. Others have sought to achieve marketing and operating efficiencies associated with larger scale organizations through joint ventures among themselves, or with hospitals and other providers. Many of these organizations are large and sophisticated, and individually may have significant influence over prices or other terms in negotiating with health plans due to their size, reputation, or quality or range of services, and the desires of consumers and employers for health plans to include them as participating providers.

Many other health professionals still practice as individuals or in small practice groups. They may prefer the autonomy and other attributes of a smaller practice setting, but many perceive that they have little or no influence in negotiating with health plans on prices or other terms for their services. These practitioners frequently seek to facilitate contracting with health plans through local Independent Practice Associations (IPAs) and other collaborative arrangements. The degree of actual integration in services or financial risk reflected by these organizations varies widely. Organizations which achieve no meaningful change in how participants provide or are paid for their services

are unlikely to benefit consumers through lower costs, improved quality or in other procompetitive respects.

The courts and Agencies have applied antitrust principles to evaluate whether these arrangements threaten to harm competition and consumer welfare, or rather have a meaningful prospect of benefiting consumers through cost savings, better management of utilization, and/or enhanced quality and coordination in the delivery of health care services. These principles have evolved substantially in recent years, and many of them formed the basis for the Department of Justice and the Commission's issuance of the Statements of Antitrust Enforcement Policy in Health Care ("Policy Statements"), which were last issued in 1996.[1] These principles have been reaffirmed through numerous Business Review Letters of the Department of Justice and in Advisory Opinions of the Commission staff. They have also been reflected in numerous government consent decrees resolving antitrust claims against joint conduct by providers in their dealings with health plans.

These policies are premised on the fundamental principle that, in the absence of procompetitive integration of services (i.e., a meaningful prospect for improving efficiency in the delivery of care, reducing costs, better managing the utilization of services, or improving quality of care), the only likely result of joint contracting by providers will be to increase or maintain prices for their services. Such conduct ordinarily is regarded as horizontal price fixing that is illegal *per se* under established antitrust principles.

[1] *Reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13, 153 (1996).

At the same time, antitrust law recognizes that joint ventures among competing health care professionals often are a lawful means of achieving efficiencies that promote competition, and that participants may jointly negotiate prices and other competitive terms of contracts with health plans where this is reasonably necessary to achieve the venture's procompetitive goals. Importantly, antitrust law requires careful consideration of the procompetitive benefits that joint contracting by a provider network or joint venture among competing health care professionals is expected to produce.

Courts and government enforcement agencies have sought to accommodate the special interests and concerns associated with joint contracting and other collaborative arrangements among health care providers within the context of established antitrust principles. *See, e.g.*, Policy Statements; Ltr. from Jeffrey W. Brennan, Asst. Dir., Bureau of Competition, to John J. Miles, Ober, Kaler, Grimes & Shiver, *Staff Advisory Opinion Re: MedSouth, Inc.* (Feb. 19, 2002) <http://www.ftc.gov/bc/adops/medsouth.htm> (hereinafter MedSouth letter) (declining to apply *per se* standard to proposed joint negotiation by competing physicians who intend to be clinically, but not financially, integrated); *All Care Nursing Service v. High Tech Staffing Services,* 135 F.3d 740 (11th Cir. 1998) (rejecting antitrust claims challenging joint bidding and contracting program to facilitate hiring of temporary nurses by twelve hospitals operating in the same county); *Levine v. Central Florida Medical Affiliates,* 72 F.3d 1538 (11th Cir. 1996) (rejecting price-fixing claim challenging physician hospital organization's joint contracting and exclusive referral arrangements used to facilitate contracts with health plans); *Blue Cross & Blue Shield United of Wisconsin v. Marshfield Clinic,* 65 F.3d 1406 (7th Cir. 1995) (rejecting, *inter alia*, price fixing claim challenging HMO's use of "most favored

nations" price provision in contracts with physicians who compete with physician group that owns HMO).

C. The Antitrust Laws Protect Against Undue Market Concentration by Both Payors and Providers

Some health care providers continue to express concerns, reinforced at the Workshop, about the power of health care payors in various markets. Two important aspects of this issue should be noted: First, observers (including those at the Workshop) have commented on the growth of large integrated delivery systems in recent years, through mergers and network formation, thus enhancing the negotiating ability of provider-members of those systems. *See*, Cara Lesser, Center for Studying Health System Change, "Recent Developments in the Health Care Markets and Policy Implications," presented at Workshop; Lawrence Wu, National Economic Research Associates, "Statement on Health Insurance: Payor/Provider Issues," presented at Workshop; Joe Simons, FTC Bureau of Competition, "FTC's Health Care Initiatives," presented at Workshop. The marketplace is, thus, arguably addressing this issue.

Second, the courts and antitrust enforcement agencies have recognized where payors have engaged (or proposed to engage) in anticompetitive conduct, and provided redress. For example, courts generally have held that the McCarran-Ferguson Act provides no exemption from antitrust law for an insurance company's agreements with third parties that supply goods or services to policyholders. *See, e.g.*, *Group Life & Health Ins. Co. v. Royal Drug*, 440 U.S. 205 (1979); *Rozema v. Marshfield Clinic*, 1997-1 Trade Cas. (CCH) ¶ 71,796 (W.D. Wis. 1997). In fact, federal and state antitrust enforcement authorities have asserted jurisdiction over provider contracts and health plan

mergers, notwithstanding the McCarran-Ferguson Act. *See, e.g., United States v. Medical Mutual of Ohio,* 1999-1 Trade Cas. (CCH) ¶ 72,465 (N.D. Ohio 1999) (final judgment and competitive impact statement, prohibiting health plan's use of "most favorable rates" provisions in contracts with hospitals).

Although there have been few direct antitrust challenges to date against mergers between health plans, federal and state antitrust law, as well as state regulation over the business of insurance, provide significant enforcement authority to monitor such transactions and prevent undue concentration among health plans that may threaten competition. One highly-publicized challenge occurred with respect to the merger of the Aetna and Prudential Insurance health plans, and the divestitures required in connection therewith. *United States v. Aetna, Inc.*, Civ. No. 3-99-CV1398-H, 64 Fed. Reg. 66647 (Justice Dep't. Nov. 29, 1999) (settlement agreement allowing merger on condition that Aetna make divestitures in Dallas-Fort Worth and Houston, Texas). There have been some other less-publicized actions pertaining to mergers among payors. *See, e.g., Proposed Acquisition of Metlife Healthcare Network of Kansas City, Inc.,* No. 95-07-13-0006 (Mo. Dep't. of Ins., Sept. 18, 1995) (order approving consent agreement requiring divestiture of St. Louis HMO); *Matter of Harvard Community Health Plan*, No. 95-0331 (Suffolk Super. Ct., Mass., Jan. 18, 1995) (assurance of discontinuance approving health plan merger subject to restrictions on future pricing and provider contracts); *Agreement between New Hampshire Department of Justice, Harvard Pilgrim Health Care, Inc., Matthew Thorton Health Plan, Inc., The Hitchcock Clinic and Dartmouth Hitchcock Health Systems* (Oct. 16, 1995) (approving health plan merger subject to restriction on exclusive contracts with primary care physicians).

Health plan mergers should continue to be subject to careful antitrust review by federal and state enforcement officials, as well as by private parties. The Section fully supports such balanced enforcement of the antitrust law in the health care industry, whether reviewing mergers among providers or payors. Mergers among health plans are -- and should be -- subject to scrutiny to address concerns about undue market power among payors. Such scrutiny should be sensitive to evolving marketplace developments, including, for example, an assessment of the possibility that barriers to entry in markets for health care insurance and financing may be higher than is generally assumed. *See*, Cara Lesser, Center for Studying Health System Change, "Recent Developments in the Health Care Markets and Policy Implications," presented at Workshop. At the same time, courts and enforcement agencies have recognized that consolidation in a broad range of markets -- including markets for health care services and health care financing -- may be procompetitive and enhance consumer welfare.

D. There Is No Need For Any Antitrust Exemption in the Health Care Industry

The Section disfavors antitrust exemptions directed at specific industry categories or conduct. Exemptions or immunities from antitrust law may insulate some market participants from competitive pressures that otherwise may lead to the most advantageous allocation of resources, and thereby promote consumer welfare. Such exemptions rarely are justified -- they often are not necessary to eliminate the risk of antitrust liability for procompetitive conduct, and the goals of such protection often can be achieved in a manner consistent with established antitrust principles and enforcement policy.

The Section has thus opposed legislation threatening to impose exemptions and immunities applicable in and outside of the health care industry. *See, e.g.*, Reports of the Antitrust Section on The Quality Health-Care Coalition Act of 1999, the Antitrust Health Care Advancement Act of 1997, the Television Improvement Act of 1997, the Major League Baseball Antitrust Reform Act of 1997 and the Curt Flood Act of 1997, and the Major League Baseball Antitrust Reform Act of 1995 (available at http://www.abanet.org/antitrust). In February 1989, at the urging of the Section, the ABA House of Delegates adopted a policy that recommended the repeal of the McCarran-Ferguson Act, which provides an antitrust exemption for the business of insurance:

> The ABA urges repeal of the current McCarran-Ferguson exemption to the antitrust laws . . . ; and recommends that states retain the authority to regulate the business of insurance, and that the federal government defer to state regulation except in unusual circumstances where the regulatory objective can only be effectively accomplished through federal involvement.

In *Identification and Description of Antitrust and Competitive Issues Raised by Key Health Care Reform Bills* (1994), the Section analyzed the positive effects of competition on reform of the health care system, favored antitrust enforcement against anticompetitive conduct affecting health care by both providers and health plans, opposed regulations that impaired competition, and opposed exemptions and implied repeals of the antitrust laws.

The Section has specifically opposed proposed legislation seeking to insulate health care professionals either from application of the antitrust laws altogether (Report on The Quality Health-Care Coalition Act of 1999), or from application of the *per se* rule (Report on the Antitrust Health Care Advancement Act of 1997), in connection with joint

negotiation with third-party payors. In the former instance, such legislation would protect price fixing, group boycotts, and market or customer allocations which occur through negotiations with health plans, and which otherwise could be deemed illegal *per se* under established antitrust principles. Such a broad protection from antitrust law has not been shown to be necessary to protect procompetitive conduct; it may result in higher prices and diminished consumer choices without improving quality or achieving other important goals in the delivery of health care; and it would not advance the policies underlying existing labor exemptions from antitrust law.

In the latter instance, legitimate, efficiency-enhancing conduct of participants in health care markets will escape *per se* condemnation under existing law and the flexible enforcement guidance contained in the Policy Statements.[2] If the conduct is blatantly anticompetitive, the *per se* rule should apply. It remains the consumer's ally against price-fixing and other manifestly anticompetitive conduct. The *per se* rule is confined to such limited categories of conduct – those which raise the most severe competitive problems -- that its elimination is unwise and unnecessary. To the extent, therefore, that legislation permitting exemptions from *per se* treatment may have been advanced in the past and current sessions of Congress, eliminating the *per se* standard would have the ironic effect of only encouraging providers to engage in the very type of conduct that some "networks" have been found to undertake: "sham" activity with the principal purpose of fixing prices or fees and raising costs to payors, employers and consumers. It

[2] The Section recognizes that some providers in the health care industry fear that threats of *per se* liability may be unjustifiably leveled against some provider networks, even if those networks create a new product or service or are clinically or financially integrated. Those providers may benefit from more guidance from the Agencies on how the *per se* rule should apply to health care provider networks.

is precisely in those instances, which involve the most egregious types of anticompetitive conduct, that the *per se* rule is most critical to effective antitrust enforcement and should be retained.

III. THE SECTION ENCOURAGES THE AGENCIES TO PROVIDE ADDITIONAL GUIDANCE ON PARTICULAR ISSUES

The Section believes that the Agencies should use every opportunity to inform the health care community of their enforcement policies, particularly as they see new trends and new issues arising in the health care industry and as the Agencies have had the opportunity to study in detail existing market conditions in a variety of contexts. The Section also encourages the Agencies to give more speeches and conduct hearings or workshops on subjects or issues where there has been little guidance in the past.

The public interest is always served by the Agencies offering thoughtful, balanced guidance that sets forth their analysis of new or complex questions, or questions on which there is little authority. The Section, however, is not necessarily encouraging a formal revision of the 1996 Policy Statements. The Section notes that those Policy Statements have generally been well received by the health care industry as providing useful and relatively detailed guidance on a number of topics in health care.

Perhaps the major criticisms that the Policy Statements have received are that they do not go far enough in their analysis of certain issues or topics, and they have not been updated or supplemented in speeches based on an assessment of marketplace developments or enforcement actions. The Section believes that more specific guidance in the following areas, whether in the form of additional speeches, workshops, hearings, or revisions to the 1996 Policy Statements, would be useful.

A. Joint Ventures to Improve Quality of Care

The Policy Statements generally offer more helpful guidance on issues arising in the joint venture area than the Antitrust Guidelines for Collaborations Among Competitors (the "Competitor Collaboration Guidelines"), which were issued in 2000. This is due principally to the Policy Statements' specific and generally more detailed application to the health care field.

For example, the Competitor Collaboration Guidelines note that there are two types of joint ventures -- the first is the type that is so likely to be harmful to competition and without significant benefits that a rule of reason analysis is not warranted and thus a *per se* rule is applied. The second is a venture where the participants in an efficiency-enhancing integration of economic activity enter into an agreement that is reasonably related to the integration and reasonably necessary to achieve its procompetitive benefits, which is subject to a rule of reason analysis. Competitor Collaboration Guidelines, §3.2.

Similarly, the Policy Statements indicate that the Agencies will generally apply the rule of reason to joint ventures where there is sufficient integration "to produce significant efficiencies, [and] any agreements on price [are] reasonably necessary to accomplish the venture's procompetitive benefits." Introduction to Policy Statements. These general principles are then applied in the Policy Statements to hospital joint ventures involving high technology or other expensive health care equipment, Policy Statement No. 2; hospital joint ventures involving specialized clinical or other expensive health care services, Policy Statement No. 3; physician network joint ventures, Policy Statements No. 8; and multiprovider networks, Policy Statement No. 9. Any perceived inconsistencies between the two sets of guidelines that arise in the health care field are

resolved in favor of the Policy Statements because they deal more directly and specifically with the issues in health care.

Although the Policy Statements address many important topics in health care, further guidance on joint ventures that are aimed at improving quality of care would be helpful to the health care industry. Such guidance could reflect substantive developments in health care markets, both generally and as understood by the Agencies in the context of recent staff opinions, business reviews or enforcement actions (or non-actions) since the most recent issuance of the Policy Statements.

Providers often complain that collaborative conduct to improve quality is misunderstood, and subject to unjustified antitrust risk. The Section recognizes the challenge of balancing traditional antitrust principles with the importance of improving quality of care. Few, if any, judicial opinions have addressed this issue effectively. As the recent empirical review of antitrust health care cases by Professors Hammer and Sage reveals, "Courts possess a limited grasp of what constitutes health care quality and how competition can be designed to further it." Peter J. Hammer & William M. Sage, *Antitrust, Health Care Quality, and the Courts*, 102 Colum. L. Rev. 545, 637 (2002).

In certain cases, the Supreme Court has rejected quality of care defenses under the Sherman Act. For example, in *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 473 (1986), the Court referred to a defense of defendant's prohibition of x-rays to insurers based on quality of care to be "flawed both legally and factually" due to the positive role of information in marketplace. In *National Society of Professional Engineers v. United States*, 435 U.S. 679, 693-96 (1978), the Court rejected a ban on competitive construction bidding based on the defense that such a ban prevented inferior work, stating that this

defense was one which the "Court has never accepted," and rejecting the defense under the rule of reason. But see *Federal Trade Comm'n. v. California Dental Ass'n*, 526 U.S. 756, 772 (1999) (commenting that restrictions on certain advertising by dentists could not be evaluated under the "quick look" framework because "the quality of professional services tends to resist either calibration or monitoring by individual patients or clients" and thus informed decision-making might benefit patients).

The Section encourages the Agencies to explore more fully how antitrust principles can accommodate the very real need to improve quality in health care. In recent years the momentum towards tightly managed care has slowed and, in many markets, has even been reversed. Consumers have demanded more choices among providers. Restrictions on access, once thought to be integral to managed care, have been jettisoned. As a result, managed care's ability to constrain payment rates appears to have diminished, and the cost of health care is escalating again at double-digit rates.

Obviously, price competition among providers should be encouraged. Nevertheless, if providers have less incentive to compete on price, overutilization and waste of health care resources may follow. In this environment, many providers have renewed their focus on improving quality. Under these circumstances, it will be important to determine if antitrust policy can help improve quality, or at least not become an impediment to improving quality. Antitrust enforcement policy that ignores quality considerations creates the potential danger of diminishing quality.

The Section suggests that the Agencies should explore in more depth the relationship between health care quality and competition. Additional workshops or

hearings may provide opportunities for better guidance on the relationship between quality and competition.

i) Need to Increase Sophistication of Market Participants on Quality Issues

If competitive forces (and antitrust policy) are to contribute to better quality in health care, participants in health care markets – both providers and payors – need to understand better the definition of "quality health care." Quality needs to be measured more accurately, and information on quality must be disseminated more widely. In the absence of a sophisticated appreciation of quality, competition will not necessarily lead to better quality. Some commentators have suggested that intensified price competition may even diminish quality, especially when quality is hard to measure (particularly for consumers), and when quality information is not readily available.

The Section does not underestimate the challenge for developing a consensus on this subject. The industry would benefit greatly, however, if the Agencies were participants in the effort to explore quality measures. Currently, quality is measured in many ways by many different players in the health care system. Organizations that play a role include the National Committee for Quality Assurance ("NCQA") (which issues report cards on health plans and others, *see, e.g.*, http://hprc.ncqa.org/menu.asp), the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"), and others. Measures include the Health Plan Employer Data and Information Set ("HEDIS") and others. People of good will can often disagree over whether outcomes are good measures, and over how to adjust for severity when comparing outcomes. There is little information available on specific hospitals and even less on particular physicians.

To the extent that some fear the antitrust laws may prohibit the development of a consensus on quality measures, the Agencies may want to reaffirm that antitrust laws are not necessarily an impediment to developing this type of information or in attempting to reach consensus over how to define and measure "quality health care." The Agencies may want to draw on the recent Antitrust/Intellectual Property hearings that discussed standard-setting activities to inform the analysis on developing consensus on quality measures in the health care industry.

ii) Competition Policy Should Encompass Improving Quality Care

If the courts and Agencies were to acknowledge the importance of improving the quality of health care as part of the competitive analysis of evaluating certain transactions or activities, the industry would have a greater appreciation for the positive impact of antitrust enforcement in the health care industry. Quality problems often occur when medical resources are overused, underused, or misused. Improving quality by reducing overuse or misuse should lead to lower health care expenditures. Even correcting underuse, in some situations, may ultimately decrease expenses to the health care system: eliminating underuse that leads to more serious diseases later can also save health care costs. From an antitrust perspective, the key issue is how to encourage such efforts at avoiding overuse, underuse or misuse of medical resources without encouraging anticompetitive collusion, or substituting governmental controls for the market. The Section encourages the Agencies to explore this issue in more detail in speeches, hearings or additional workshops.

iii) Focus on Financial Integration and Quality Concerns

The Agencies have devoted much thought and attention to payment mechanisms in the context of concerns about price competition. Candidly, however, the Agencies could provide more guidance to help address the effects on quality that such payment mechanisms may have.

Provider payment systems (fee-for-service, salary, discounts with withholds, global fees, capitation) each create quite different incentives for providers. Some critics charge that the incentive in capitation, for example, is to provide as little care as possible so as to maximize profit. *See,e.g.*, *Marshfield Clinic*, 65 F.3d at 1409 ("The method of pricing [used by HMOs] gives the HMO an incentive to minimize the procedures that it performs, since the marginal revenue it derives from each procedure is zero.") (Posner, C.J.); *Crossing the Quality Chasm, A New Health System for the 21st Century* (Institute of Medicine 2001). Despite disclaimers by the Agencies, capitation is perceived by many as having a "preferred status" in antitrust analysis, or, at least, the Agencies appear to presume that capitation equals risk sharing in every case. *See* Policy Statement Nos. 8 & 9. An antitrust enforcement attitude that appears to favor capitation must be sensitive to the effect on quality such an emphasis may create.

Some people believe the Policy Statements also present an "either/or" choice between financial integration and clinical integration as the framework necessary before otherwise competing providers can engage in network pricing. Market reality may often dictate a blending of both types of integration. Consequently, the Agencies may wish to consider explicitly discussing whether some combination of reduced financial and clinical integration may also be an acceptable basis for a rule of reason analysis of joint pricing, or clarifying that the indicator of integration does not have to be either solely

financial or solely clinical. For example, would the Agencies consider some type of sliding scale analysis of financial and clinical integrative activities that could justify a rule of reason approach to joint pricing? While the Section recognizes the difficulty in adopting any hard and fast rules in this area, further exploration and discussion of a "blended" approach to integrative activities may be useful to educating providers and payors.

iv) Collaboration on Clinical Guidelines Among Providers and Payors

Some commentators have observed that many quality problems arise from inadequate attention to the evidence base of medicine and to a failure to develop systems solutions to increase adherence to best practices. *See To Err Is Human: Building a Safer Health System* (Institute of Medicine 2000). Evidence-based medicine relies on a systematic review of the published literature to develop clinical guidelines, rather than on individual clinicians relying on their own individual experiences.

The increasing importance of evidence-based medicine has several ramifications for antitrust policy. First, evidence-based clinical guidelines are more easily developed in large health care delivery systems, as these are more likely to have the necessary data, resources and management structures. Many health care providers and payors are simply too small to develop, implement and update clinical guidelines. Moreover, organizations that integrate health care and financing may have some advantages in developing and implementing clinical guidelines. Accordingly, the Section encourages the Agencies to explore how antitrust policy can accommodate the growth and integration necessary to build organizations that are capable of developing and implementing such quality

systems, while adhering to the traditional and appropriate concern of avoiding the creation of unreasonable market power in an organization.

Second, collaboration is often an indispensable way to develop clinical guidelines. Those providers who practice as individuals and in small groups must cooperate to develop and implement clinical guidelines (and to make necessary investments in information systems and other tools) or they will risk practicing "horse and buggy medicine." *See Marshfield Clinic*, 65 F.3d at 1416. Even large providers (such as multi-specialty groups) and large payors can benefit from cooperation on the development of clinical guidelines. In theory at least, the greater the collaboration, the greater the likelihood better guidelines will be developed. Collaboration among providers and payors to develop guidelines can take advantage of the access each one has to different data.

Such collaboration, obviously, can raise antitrust issues. If competing providers cooperate on the development of clinical guidelines, and leave their implementation to the individual decisions of the providers, little antitrust risk should be created. Indeed, Policy Statement No. 4 would appear to acknowledge the benefits of providers developing suggested practice parameters – standards for patient management and for development of protocols that increase quality and efficiency. If providers take a further step, however, and agree jointly to implement certain guidelines, Policy Statement No. 4 seems to indicate that more serious antitrust issues can arise, unless the guidelines are adopted in the context of an integrated network, because a collective imposition of such standards on payors may give rise to a potential boycott.

Arguably, by developing and implementing practice guidelines, the providers have eliminated competition among themselves on how patients are to be treated. This is less likely to raise a competitive issue if a guideline is supported by the overwhelming consensus of scientific evidence. If a guideline has no overwhelming consensus, then the adoption and implementation may eliminate competition on an aspect of quality.

Payors obviously have an interest in the development and implementation of clinical guidelines as well. Such guidelines lead to better outcomes (satisfied patients) and can lead to lower costs (satisfied payors and employers). If different payors adopt different clinical guidelines in the same geographic area, however, providers whose patients are covered by different payors will have a variety of clinical guidelines they are expected to consult. It may be more efficient to adopt a common set of clinical guidelines instead of expecting providers to familiarize themselves with competing guidelines.

While the Section recognizes the potential issues of group boycotts by providers who demand payors' acceptance of provider-created protocols, there may be opportunities for the Agencies to acknowledge the benefits of collective discussions of treatment protocols among payors and providers that will inure to their mutual benefits and to the benefit of patients, and will stop short of illegal boycotts. The Section suggests the Agencies may want to explore how such collaborative efforts to develop clinical guidelines may coexist with antitrust enforcement policies. Guidance in this area naturally dovetails with the issue of "clinical integration" because some providers and payors will want to go beyond developing guidelines to implementing them jointly. The Agencies may want to offer the industry an opportunity to engage in a meaningful

dialogue on when collaboration on quality is efficiency enhancing, and when it is not. Regardless of whether the Agencies go so far as to issue a formal policy statement on formulation of clinical guidelines by groups of providers and/or payors, the Section believes that further discussion (through workshops or hearings) and more guidance (through speeches or staff advisories or business review letters) on this issue would be a meaningful service to the industry.

Traditional antitrust analysis should be sufficiently comprehensive to accommodate the concerns about improving quality of care. The Agencies should consider leading the effort at encouraging more analysis and understanding of the role that competition plays in promoting quality. A better appreciation for the role health care competition policy plays in promoting quality will likely lessen the volume of critics who claim that antitrust policy interferes with quality and may also muffle the cries for special exemptions from the antitrust laws for the health care industry.

B. Clinical Integration

Another topic that the Agencies addressed to some extent in the Policy Statements, but that would benefit from further clarification and amplification, is the description of recognizable efficiencies or benefits from "clinical integration." The Policy Statements set forth the Agencies' analytical approach to physician network joint ventures involving independent and competing health care providers who seek to contract collectively with health care plans. The Policy Statements indicated that sufficiently integrated physician network joint ventures will not be deemed to be *per se* illegal under the antitrust laws, but will be evaluated under the more flexible rule of reason standard.

The Policy Statements stated that there are two types of integration which can possibly make physician network joint ventures "likely to produce significant efficiencies that benefit consumers": substantial financial risk sharing and clinical integration. Financial integration had previously been mentioned as an acceptable integration method for physician network joint ventures in the earlier 1994 version of the Policy Statements. The Policy Statements contained a fairly detailed description of the potential financial risk sharing integration methods and, subsequently, the Agencies have issued numerous advisory opinions and business review letters relating to various financial integration programs proposed by physician network joint ventures. As a result, there is a substantial amount of guidance for physician network joint ventures interested in utilizing financial risk sharing methods.

On the other hand, the Agencies' acceptance of clinical integration as a basis for rule of reason analysis for physician network joint ventures was recognized publicly for the first time in 1996. The Policy Statements declared that physician networks that do not involve the sharing of substantial financial risk nevertheless might jointly set prices and negotiate with health care plans if "integration through the joint venture creates significant efficiencies and the venture on balance, is not anticompetitive." In addition, any agreements on price must be "reasonably necessary to realize those efficiencies." Policy Statement No. 8.B.1. The Agencies explained that clinical integration can be shown by programs designed "to evaluate and modify practice patterns by the network physician participants and create a high degree of inter-dependence and cooperation among the physicians to control costs and ensure quality. Such a program could include utilization review, evaluation of individual and aggregate performance, efforts to modify

behavior where necessary, case management, review of hospital stays, and development of practice standards and protocols." *Id.*

The Policy Statements contained one hypothetical example of satisfactory clinical integration and, since 1996, the Agencies have issued only one advisory opinion analyzing a clinical integration program. In February 2002, the Commission staff issued an advisory letter regarding the proposed clinical integration program of MedSouth, Inc., a physician IPA located in the Denver, Colorado, area. In this MedSouth advisory letter, the Commission staff indicated that it would not challenge at this time MedSouth's proposal to set joint prices in connection with a clinical integration program because MedSouth appeared to have the potential to improve the quality and effectiveness of health care services and to provide benefits to consumers. Nonetheless, the Commission staff also warned that it would look closely in the future at the actual competitive impact of MedSouth's activities.

MedSouth had indicated that its clinical integration program was designed to result in lower costs, higher quality and more efficient delivery of health care services by its members. The two major parts of MedSouth's clinical integration program were (1) a web-based electronic clinical data records system that would permit MedSouth physicians to access and share clinical information relating to their patients, and (2) the adoption and implementation of clinical practice guidelines and performance goals relating to the quality and appropriate use of services provided by MedSouth physicians. The first part would require a substantial capital investment by the member physicians to establish the computer network to enable the primary care and specialist physicians to share patient clinical information. The second part of the program involved the

development of clinical protocols covering the various practice areas of the member physicians and measurable performance goals relating to the quality and appropriate utilization of services that are linked to those protocols. MedSouth proposed to secure the physician members' commitment to adhere to those protocols in their office and hospital practices, to review the performance of MedSouth physicians individually and collectively with respect to those goals, to assist members in meeting those goals, and, if necessary, expel physicians who did not meet the goals.

Thus, in the six years since the Policy Statements were issued, the only sources of legal guidance available to health care providers interested in developing clinical integration programs are the one hypothetical example contained in the Policy Statements and the MedSouth staff advisory letter. In view of the limited amount of specific guidance on the issue of clinical integration, the Section suggests that it would be beneficial for the Commission to conduct additional workshops and/or discussion groups regarding clinical integration programs. While the MedSouth advisory letter suggests a very rigorous and fairly burdensome approach for establishing a clinical integration program, it is possible less rigorous and less burdensome programs can be established that still satisfy the standards set forth in the Policy Statements and are consistent with the ancillary restraints doctrine in case law. Such workshops or discussion groups would furnish an opportunity for providers who are currently using clinical integration programs or contemplating the development of such programs to discuss the kinds of clinical integration programs that can or cannot be developed successfully. The workshops or discussion groups could also provide an opportunity for the Agencies to discuss the types of clinical integration characteristics that may have resulted in Agency decisions not to

challenge certain networks in the past. Without revealing the specifics of any investigation, the Agencies could provide a service to the health care community in sharing such observations on the types of clinical integration that appear to have addressed the issues of concern to the Agencies.

For example, amplification of circumstances in which a combination of physicians was deemed to have been sufficient to create a "new product" would prove very useful. *See* Policy Statements, n. 36 & 46. Additional detail on the means by which it can be demonstrated that agreements on price are reasonably related to the achievement of efficiencies would also prove useful for assisting practitioners to determine *ex ante* when the rule of reason is likely to apply. Arguably, attempting to determine when agreements on price are "reasonably related" to achieving efficiencies is one of the murkiest areas of antitrust analysis. Therefore, further discussions by the Agencies on this topic, perhaps with examples or hypotheticals, would serve to enlighten the provider community. Along these same lines, a discussion addressing clinical integration in the context of physician/hospital relationships where a single hospital provides the opportunity for clinical integration among its physician staff would be helpful.

In sum, the Section believes it would be highly beneficial if the Agencies engaged in a more robust discussion and exploration of how clinical integration can qualify for a rule-of-reason analysis in the context of joint price negotiation.

C. Group Purchasing

The role of group purchasing organizations ("GPOs") in the health care system has come under increased scrutiny in the last year, with allegations of anticompetitive behavior levied against a number of GPOs. Complaints by small manufacturers of

medical devices, articles in the *New York Times*, and a hearing before the Senate antitrust subcommittee have contributed to this heightened scrutiny. During the recent Workshop, individuals representing GPOs, hospitals, small device manufacturers, and academia presented their – sometimes conflicting – positions to the Commission on the role of the competitive effects of GPOs.

While the Policy Statements analyzed antitrust issues related to membership in GPOs, they did not provide significant guidance on the issue at the forefront of today's debate -- the alleged exclusionary effect of GPOs on non-GPO suppliers. The Section takes no position on the validity of allegations of anticompetitive conduct arising out of GPO-negotiated contracts. The Section notes, however, that if the Commission considers this issue in more detail, it may want to examine such topics as the propriety of revising the Policy Statements to provide guidance about GPOs' appropriate conduct, evaluation of allegations of exclusive dealing and anticompetitive effects in specific markets, determination of how to measure GPOs' market share, determination of the exact manner in which small device manufacturers are supposedly denied access to hospital decision makers, and whether such denials are the natural consequence of a competitive bidding process.

i) Overview of GPOs

GPOs are firms designed to aggregate the purchases of members in order to negotiate lower prices for covered products (*e.g.*, medical devices, pharmaceuticals, and commodities) from vendors. In addition to contracting directly with vendors, most hospitals utilize a GPO, some more than one, in facilitating the purchase of varying quantities of medical supplies. In order to increase leverage with suppliers and to achieve

scale economies, GPOs tend to select a limited number of manufacturers and vendors of a product to offer to their members. By narrowing the product selection available for purchase by member hospitals, GPOs often are able to negotiate lower prices.

GPOs vary significantly in size, scope, and operation. According to the Health Industry Group Purchasing Association ("HIGPA"), there are approximately 800 GPOs in the United States that negotiate on behalf of nearly 2000 hospitals.[3] GPOs do not generally purchase supplies from vendors for resale to member hospitals. Instead, a GPO solicits bids from multiple vendors based on the needs of its member hospitals. After the GPO negotiates a supply contract with the winning bidder, its member hospitals purchase the supplies directly from the supplier at the terms specified in the GPO-negotiated contract. The GPO is financed for its services primarily through administrative fees paid by suppliers and other vendors. The fees are typically calculated as a percentage of a vendor's sales to each hospital, and are often distributed to member hospitals after accounting for the GPOs administrative costs.

Though there are hundreds of GPOs in the nation, HIGPA reports that only about 30 negotiate substantial contracts on behalf of their members.[4] The contracts negotiated

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[3] *See* Robert Betz (President & CEO, Health Industry Group Purchasing Association), Address at Workshop ("Betz Statement"), at 4 (Sept. 10, 2002) (statement submitted by author) (citing Appendix A, Herbert Hovenkamp, Competitive Effects of Group Purchasing Organizations' (GPO) Purchasing and Product Selection Practices in the Health Care Industry (April 2002) ("Hovenkamp Report")).

[4] Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovations?: Hearing Before the Senate Judiciary Committee, Subcommittee on Antitrust, Competition, and Business and Consumer Rights, 107th Cong. 56-57 (April 30, 2002) (statement by William J. Scanlon, Director, Health Care Issues, General Accounting Office) (submitting with testimony report on "Group Purchasing Organizations: Pilot Study Suggests Large Buying Groups Do Not Always Offer Hospitals Lower Prices") ("GAO Pilot Study) ("According to the [HIGPA], hundreds of GPOs operate today, but only about 30 negotiate sizeable contracts on behalf of their

by GPOs on behalf of member hospitals vary significantly from one GPO to the next. According to some critics, many GPO arrangements include provisions that effectively foreclose member hospitals from contracting with device makers not "covered" by the GPO.

ii) Antitrust Enforcement Policy Regarding Joint Purchasing Arrangements

Policy Statement No. 7, relating to the Agencies' policy on joint purchasing arrangements among health care providers, begins by recognizing that most joint purchasing arrangements among hospitals do not raise antitrust concerns. According to the guidelines, such collaborations typically allow the participants to achieve efficiencies that benefit consumers. The Policy Statement notes that, by virtue of volume discounts, reduced transaction costs, and access to consulting advice, joint purchasing arrangements may yield benefits that otherwise might not be available to each participant acting on its own.[5]

The Agencies provide an antitrust "safety zone" for certain group purchasing programs. Policy Statement No. 7 provides that, "absent extraordinary circumstances," the Agencies will not challenge joint purchasing arrangements where (1) purchases by participants account for less than 35 percent of the total sales of the product or service in the relevant market; and (2) the cost of purchases through a GPO accounts for less than 20 percent of each of the participant's total revenues. According to the Policy Statement, the purposes underlying the two conditions are to guard against the possibility of monopsony power and situations that facilitate price fixing.[6]

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members").

[5] Policy Statement No. 7.

[6] *See id.*

Joint purchasing arrangements that fall outside the safety zone do not necessarily violate the antitrust laws. Rejecting a *per se* approach, the Policy Statement suggests three safeguards that those creating joint purchasing arrangements can adopt to mitigate anticompetitive concerns: (1) not requiring members to use the arrangement for all of their purchases of particular goods or services; (2) not using an employee of a participant to negotiate a contract with vendors; and (3) assuring that communications between the purchasing group and individual participants are kept confidential and are not discussed with, or disseminated to, other participants. Policy Statement No. 7 notes that "[t]hese safeguards will reduce substantially, if not completely eliminate, use of the purchasing arrangement as a vehicle for discussing and coordinating the prices of health care services offered by the participants." Adopting these safeguards "will help demonstrate that the joint purchasing arrangement is intended to achieve economic efficiencies rather than to serve an anticompetitive purpose." The Statement concludes that "entry barriers to forming new groups currently are not great," and that, "in most circumstances," joint purchasing arrangements do not need to be opened to all competitors in the market. Where excluded competitors are "unable to compete effectively without access to the arrangement" and competition is harmed, however, the Policy Statement indicates that antitrust concerns will exist.[7]

iii) Current Debate Over Joint Purchasing Arrangements

Commentators have noted that GPOs have grown rapidly and consolidated.[8] Most of the criticism of anticompetitive behavior by GPOs has focused on the business

[7] *Id.*
[8] *See, e.g.*, GAO Pilot Study at 1.

practices of the two largest GPOs, Premier and Novation – depending on the source, representing a combined market share of either 27 percent or 54 percent.[9]

The contracting policies of these GPOs have recently been accused of being anticompetitive, particularly with respect to GPO-negotiated contracts between hospitals and vendors for the provision of medical devices.[10] Trade organizations and respected

[9] Hovenkamp Report, at 4; Einer Elhauge, The Exclusion of Competition for Hospital Sales Through Group Purchasing Organizations, at 14-15 (June 25, 2002) (unpublished report, *available at* http://www.medicaldevices.org/public/news /releases/Elhauge_GPO_Report.pdf) ("Elhauge Report").

[10] Many issues raised by critics of GPOs are only tangentially related to antitrust concerns. For example, criticisms of the efficacy of GPOs in securing better pricing and of alleged conflicts of interest of GPO executives do not directly raise antitrust issues.

antitrust scholars have spoken out in favor of both the complaining manufacturers and the GPOs.

Small manufacturers of medical devices allege that they have been denied access to the decision makers at hospitals due to the exclusionary contracts negotiated by certain GPOs. The Medical Device Manufacturers Association ("MDMA"), bolstered by reports by Professor Einer Elhauge,[11] that it partially funded, argues that certain GPOs have become gatekeepers that sell and control access to their member hospitals by virtue of exclusionary GPO-negotiated agreements.[12] In certain markets, MDMA and Professor Elhauge argue that large vendors pay elevated fees to the GPOs, and the GPOs create incentives for hospitals not to purchase products from non-GPO vendors. This situation allegedly restricts competition, increasing the GPOs' market power, restraining market entry, preventing new entrants from reaching economies of scale, reducing investment capital for medical device innovation and development and increasing health care costs.

The GPOs respond that they only act on behalf of their member hospitals and lack both the incentive and ability to impair competition. HIGPA, which represents nearly all GPOs and their trading partners, argues that (1) the market in which GPOs operate is highly competitive (in fact, most hospitals belong to several GPOs), (2) the GPOs foster competition and generally do not require members to purchase all supplies through the GPO, and (3) GPO contracting practices are merely incentive arrangements

[11] *See generally* Elhauge Report.
[12] *See* Larry R. Holden (President, Medical Device Manufacturers Association), Presentation at the Federal Trade Commission's Hearing on Health Care and Competition Law and Policy Workshop ("Hospital Group Purchasing Organizations") at 15 (Sept. 10, 2002) (presentation submitted by author).

encouraging members such as hospitals to purchase larger volumes through GPO contracts. HIGPA's arguments are themselves bolstered by a report prepared for it by Professor Herbert Hovenkamp.

iv) Potential Future Inquiry by the Agencies

As noted previously, only a few of the recent concerns expressed about GPOs relate to antitrust issues. Given the allegations levied against GPOs, if the Agencies decide to examine these allegations more fully, they might provide further clarification of their views about joint purchasing arrangements in light of the current debate about their impact on competition in the health care industry.

In particular, the Agencies may want to examine when GPO contracts may have exclusionary effects at either the supplier or the purchaser level. They may also want to consider whether certain provisions in GPO-negotiated contracts amount to *de facto* exclusivity at either level. The Agencies might choose to consider whether certain commitment requirements amount to *de facto* exclusivity or can otherwise cause anticompetitive harm by raising rivals' costs. The Section recognizes that the previous Policy Statements on the subject of exclusivity (e.g., Statements 8 & 9 in the context of provider networks) may enlighten this inquiry.

Another area the Agencies might consider would be the appropriate approach to measuring market shares of GPOs. Professors Elhauge and Hovenkamp, in their work in this area, disagree on the scope of possible foreclosure at issue, postulating that the combined national shares of Novation and Premier may either be as low as 27 percent or as high as 54 percent. These competing views raise issues such as what is the proper scope of the market; what types of products should be included in the market; and what

types of purchasers should be included in the universe for measuring market shares. Given the importance of market shares in assessing the percentage of the market foreclosed (and thus, whether an exclusivity arrangement constitutes anticompetitive conduct), the Agencies might appropriately choose to examine further how they would approach measuring the market shares of GPOs.

If the Agencies conduct a further inquiry, they may also choose to explore whether small device manufacturers or other suppliers are actually being denied access to the decisionmakers at hospitals due to GPO-negotiated contracts. If vendors have free access to hospital decisionmakers, GPO purchasing is unlikely to have anticompetitive effects, because vendors are free to persuade the hospitals to purchase less costly or more innovative products. If, on the other hand, access to those decisionmakers is denied, the selection of a particular product by a GPO may become more critical. In response to the claims that access to hospital decisionmakers is effectively denied to smaller device manufacturers, the Agencies may want to explore the nature of such denials, whether such denials are merely the result of a competitive bidding process, and the competitive impact of GPO-negotiated contracts in the market as a whole.

D. Virtual Mergers or Joint Operating Agreements

There has been a good deal of discussion in recent years concerning hospitals that have formed a variety of affiliations, networks, joint ventures, partnerships or new corporations that result in joint marketing of hospital services, but may not be viewed as a formal "merger" of the hospitals. These arrangements have often been described as "virtual mergers." While there is some reference to hospital mergers in the Policy Statements, the subject of virtual mergers or joint operating agreements among hospitals

is not discussed in the Policy Statements. The decision in *New York v. Saint Francis Hospital*, 94 F. Supp.2d 399 (S.D.N.Y. 2000), holding that a hospital joint venture constituted a *per se* violation, is one of the few reported decisions addressing this issue.

It is our understanding that the Agencies have investigated other joint hospital arrangements or "virtual mergers" without taking any enforcement actions. The Agencies' perspectives and enforcement positions on this issue would provide useful guidance to industry participants.

Among other things, an exploration of the Agencies' position and an explication of their views on the application of the *Copperweld* doctrine in the context of so-called "integrated delivery systems" could provide very helpful guidance to practitioners. Such guidance could address such issues as various factors bearing upon single-entity analysis, including the importance of formal corporate structure among the members of the network (sole membership, brother-sister not-for-profit corporations, etc.), as distinct from substantive considerations inherent in the notion of a "unity of interest." Such guidance could also, for example, treat the question of whether, in the not-for-profit context, the mere creation of administrative efficiencies, without corresponding clinical integration or efficiencies, creates a sufficient "unity of interest" to warrant single-entity treatment under *Copperweld*.

E. Monopoly Conduct

Another area not addressed in the Policy Statements is monopoly conduct as illustrated by tying, leveraging, exclusive contracts, and refusals to deal. This area has been the subject of much private litigation. *See e.g.,, Rome Ambulatory Surgery Center LLC v. Rome Memorial Hospital, Inc.*, No. 5:01-CV-23 (N.D.N.Y. 2002); *Coventry*

Health Care of Kansas, Inc. v. Via Christi Health System, Inc., No. 01-261-JTM (D. Kan. 2001). The Section recognizes that there is at least the perception that providers or health care industry participants may have significant market power. A related issue is whether exclusive contractual provisions between hospitals and managed care plans can raise substantial competitive and quality concerns. The Agencies have been particularly silent in this area, and it would be helpful to know whether they have not had the opportunity to review such activities, or they do not see any competitive harm resulting from such conduct.

In the Commission's retrospective merger review, the Commission may have an opportunity to elaborate further on its views of these issues. Further guidance would be very beneficial to the industry.

IV. CONCLUSION

The Section appreciates the opportunity to present its views on some of the important issues examined by the Commission at the recent Workshop. If the Commission conducts additional hearings on the role of antitrust in the health care industry, the Section pledges its cooperation. The Section also reaffirms its goal to assist in educating the bar and the public on the positive contributions that competition and the antitrust laws can play in maintaining and improving the country's health care system.