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March 26, 2004

Via Federal Express

Cecile T. Kohrs
Office of General Counsel
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Re: California Association of Physician Groups' Submission

Dear Cecile:

Please find enclosed the supplemental submission of the California Association of Physician Groups ("CAPG") in connection with the FTC/DOJ Joint Hearings on Health Care and Competition Law and Policy. CAPG would welcome the opportunity to discuss these issues further with the FTC staff.

Sincerely,

Richard A. Feinstein

cc: Matthew Bye
Donald Crane

Enclosure

Clarifying the Health Care Statements'[1] Policies of Clinical Integration and Ancillarity

Submitted by the California Association of Physician Groups
March 2004

As recently described by Chairman Muris, the FTC's antitrust enforcement activity directed towards physician groups has been "aggressive."[2] In the last three years, the FTC has initiated numerous enforcement actions involving physician organizations. The principal allegation in these cases has generally been the same: competing physicians have joined together, without sufficient clinical or financial integration, for the purpose of negotiating higher reimbursement rates from payers.

In accordance with the Health Care Statements, an IPA comprised of competing physicians can negotiate on behalf of the physicians contracts with payers (including reimbursement rates) without fearing per se condemnation of such negotiations, so long as (1) the IPA is clinically integrated and (2) price-related negotiations are "reasonably necessary" (or ancillary) to achieve the benefits of the clinical integration.[3] If these conditions exist, the FTC will assess an IPA's negotiations using a rule of reason analysis and will not challenge the negotiations on a per se theory. While this does not automatically legalize the IPA's joint

[1] In this paper, we refer to the DOJ's and FTC's *Statements of Antitrust Enforcement Policy in Health Care* at the "Health Care Statements."

[2] William M. Sage, *Protecting Competition and Consumers: A Conversation with Timothy J. Muris*, Health Affairs, Vol. 22, Issue 6 (2003), 101-110 (available at www.ftc.gov).

[3] Health Care Statements at Statement 8 § B.1.

negotiations, as a practical matter it makes an FTC challenge of the IPA's negotiations less likely, as the FTC would bear a much greater burden in pursuing a rule of reason (as opposed to a per se) challenge to a joint venture.[4] But what exactly it means to be "clinically integrated" and for such integration to be ancillary to joint negotiations has yet to be adequately explained by the FTC or a court.

The purpose of this paper is to identify indicia of clinical integration and circumstances under which such integration can be deemed ancillary to joint negotiations that would satisfy the Health Care Statements requirements for rule of reason analysis. Moreover, in this paper, we suggest that the Statements' clinical integration and ancillarity requirements ought not to be viewed separately, but should instead be assessed together. The greater an IPA's integration, and the more resources devoted to the integration, the more likely the IPA's integration is ancillary to joint negotiation of payer contracts.

Endorsing this concept as well as providing clarity as to the Health Care Statements' clinical integration and ancillarity requirements will, we believe, foster physician participation in legitimate, integrated IPAs. This is particularly important to California-based physician groups. California is experiencing a rapid growth in PPO products.[5] In the PPO context, and unlike

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[4] This perspective is supported by Commissioner Leary, as he believes that "[t]he initial characterization [of a collaboration], either as a cartel or a joint venture, is likely to be outcome determinative because it is so much harder to prosecute a rule of reason case against a joint venture." Commissioner Thomas B. Leary, Efficiencies and Antitrust: A Story of Ongoing Evolution, Remarks Before the ABA Section of Antitrust Law (Nov. 8, 2002), at 14 (available at www.ftc.gov). Accordingly, if an IPA "can make a plausible case for potential group efficiencies, [it is] likely to survive agency scrutiny." Id.

[5] The term "PPO" is used throughout this paper to refer to fee-for-service products. The term "HMO" is used throughout this paper to refer to capitated products.

HMO products, payers often do not pass financial risk, claims, and payments through an IPA.[6] This inherently limits the ability of IPAs to structure a viable risk-sharing model in connection with PPO products and makes clarity as to the FTC's view of the Statements' clinical integration and ancillarity requirements critical.

1. Clinical Integration.

There can be no legitimate dispute that an integrated IPA, when compared to the delivery of care of single physicians or small group practices, improves the operational efficiency and quality of care delivered by the physicians within the IPA.[7] According to the American Medical Association, more than 75 percent of physicians nationally practice in groups of eight or fewer physicians.[8] This means that, absent participation in some form of larger physician organization (such as an IPA), physicians will generally not be able to coordinate the delivery of care across multiple specialties and diagnoses. Undoubtedly this results, at least to some degree, in poor coordination of services, delivering unnecessary care, and reduced quality – especially with regard to fee-for-service PPO products. For example, a patient with a chronic multisystem disease such as diabetes who has associated eye, kidney, and heart problems is typically seen by a number of specialists with poor coordination of their efforts. While the primary care physician

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[6] As discussed in the attached "IPA Model for Clinical Integration in a PPO Setting," authored by Bartley Asner, M.D., California-based IPAs generally would prefer that payers submit PPO physician payments through the IPAs (as opposed to directly to physicians), which would enable the IPAs to structure viable risk arrangements and to more easily review physicians' delivery of care. But payers are resisting this payment submission process.

[7] It is worth noting that forming an IPA can be a superior approach to integration than merging group practices into a single practice. Merging practices is often expensive, complex, and can reduce geographic coverage.

[8] American Medical Association, Physician Socioeconomic Statistics, 2000-2002 edition.

in theory should be coordinating this care, in the typical PPO environment, there is no expectation that the patient sees the primary care provider or that the primary care provider will in fact serve a coordinating function. The patient will likely self-refer to specialists, ensuring that the care cannot be coordinated. In addition, in the PPO environment, a physician often admits a patient to the hospital without the knowledge of other physicians who have participated in the outpatient care of that patient.

On the other hand, when multiple specialties participate in an IPA that is at least partially integrated clinically, care will almost certainly improve and the costs of delivering care will almost certainly be reduced. In the mulitsystem disease example described above, a primary care physician is much more likely to serve a true coordinating function, even in a PPO setting. Moreover, the primary care physician and specialists will likely have access, through a shared information system, to the same records of the patient, providing details as to other physicians' diagnoses and treatments. This will ensure that the physicians will not duplicate services or treatments and maximize the use of ambulatory outpatient settings.

Simply put, clinical integration is procompetitive.[9] This, presumably, was the reason that the FTC and DOJ revised the Health Care Statements in 1996 to explicitly recognize clinical integration as an independent basis upon which to justify joint negotiation of physician contracts.[10] What remains unclear is how much clinical integration is necessary under the Health

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[9] For one description of how clinical integration can improve outcomes and efficiency, see the attached "IPA Based Model for Clinical Integration in a PPO Setting."

[10] In their original form (issued in 1992), the Health Care Statements only recognized financial integration as a basis for an IPA to negotiate payer contracts on behalf of competing physicians. By recognizing clinical integration as a second, independent basis upon which to justify such joint negotiations, the 1996 revisions to the Statements reflected a meaningful (and wise) policy shift.

Care Statements to at least preclude the application of a per se theory to an IPA's contract negotiations. While we recognize the difficulty in articulating a bright line rule as to the necessary level of clinical integration needed to warrant a rule of reason analysis, below are indicia of integration the FTC could consider in assessing the contracting activities of an IPA:[11]

a. Development and Adoption of Clinical Protocols.

IPA physicians and staff members can develop clinical protocols that delineate utilization and quality goals for various diagnoses. These protocols can be reviewed periodically and updated as needed to reflect efficiency improvements, improved utilization performance, and technological and treatment advances. Moreover, the IPA can take into account national, regional, and local variations in treating diagnoses, assess the underlying reasons for the variations, and adjust the protocols accordingly.

Developing and revising protocols typically requires that IPA member physicians from multiple specialties volunteer to serve on a committee that reviews the protocols, utilization trends, literature describing medical and treatment advances, and physician performance against the protocols (to assess the need to revise the protocols). It also requires assigning management from the IPA (or consultants) to oversee and participate in the protocol development/review process.

b. Clinical Care Review.

An IPA may review its physicians' delivery of care to ensure compliance with efficiency and quality goals identified in clinical protocols. Conducting such clinical care review typically

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[11] This is not to suggest that an IPA must conduct all of the described activities to be considered "integrated." These are simply examples of integration-related activities relevant to an assessment of whether an IPA is sufficiently integrated – on a continuum of "clinical integration" – to jointly negotiate payer contracts without fearing per se condemnation.

requires the following resources: (1) acquiring an information system to collect, store, segment, and report clinical information by physician, patient, and diagnostic category, (2) hiring staff to oversee the information system, input data into the information system, and analyze data trends, (3) and analyzing reports to identify physicians whose delivery of care does not comport with an IPA's protocols. Moreover, where payers do not reimburse PPO physicians for care through an IPA (as is often the case in California) – meaning that physicians must individually submit claims to payers – additional burdens are borne by the IPA and physicians in order to conduct clinical care review. These include individual physicians and practice groups submitting claims to an IPA (typically on a monthly basis) as well as IPA personnel standardizing data submitted by the physicians before inputting it into an information system.

Valid, statistically significant data concerning physicians' delivery of care is critical to conducting clinical care review and physician performance profiling. In this regard, when an IPA aggregates large numbers of patients across multiple plans, analyses of utilization data will be more meaningful. This can be a benefit of a larger IPA comprised of multiple specialties in an area.

c. Management Oversight to Ensure Adherence to Protocols.

Through clinical care review, an IPA can ensure that individual physicians adhere to protocols by identifying any physicians that have not met quality and cost goals. Such "outliers" can be contractually obligated to improve performance or face expulsion from the IPA. Prior to expulsion, an IPA may have programs to assist outliers in improving performance such as more frequent monitoring of care and directing physicians to care management materials (which may have been collected in developing protocols).

Another means to encourage physician adherence to protocols is to link physician compensation to such compliance. In California, this incentive is prevalent with HMO products, but not with PPO products, which limits IPA's ability to withhold payment from a PPO physician.[12] Nonetheless, even without such a direct financial incentive, a physician's contractual commitment to abide by an IPA's clinical protocols as well as a commitment to work with an IPA to improve the delivery of care in order to meet protocols (if needed) will almost certainly result in improved, cost effective care: it is highly unlikely that a physician will consistently want to be singled out for delivering inefficient or low quality care and will improve his performance accordingly.[13]

d. Credentialing.

IPAs can credential physicians to ensure that its network is comprised of high quality physicians. Physician credentialing typically entails reviewing a physician's education, licenses, hospital privileges, and malpractice history. It also involves, typically, having an IPA representative or consultant (often a clinical nurse) conduct an office site in which a physician office is evaluated on the basis of administrative categories (such as average wait time for appointments), record keeping, emergency procedures, cleanliness, and safety. A physician who does not score well on this review will typically be evaluated by a peer review committee, which

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[12] In California, in conjunction with seven health plans, roughly 300 physician groups and IPAs are participating in a pay-for-performance program, in which physician groups are paid a bonus if they meet specified goals concerning quality of care, patient satisfaction, and use of information technology. This statewide program is confined to HMO products in large part because the health plans pay physicians through IPAs. If the plans were willing to pay physicians through IPAs with regard to PPO products, this groundbreaking quality initiative could be extended to the PPO arena. Nonetheless, some of the benefits from the program are likely spilling over to PPO products.

[13] Along these lines, data show that publishing physician performance against benchmarks has a measurable effect on the delivery of care for those physicians who score below average.

assesses the value of keeping the physician within the network. Physician recredentialing is typically conducted by an IPA once every several years.

e. Existing Integration Experience.

Finally, an IPA's experience in delivering a clinically integrated product to the market should be considered. If an IPA, for instance, contracts on behalf of an integrated physician network to provide care for payers' HMO products and seeks to transition this network to contract for PPO products as well, the IPA should be afforded more latitude (relative to a start-up IPA) in terms of when it begins negotiating payer contracts during this transition. Because at least some of the benefits of the IPA's HMO integration will spill over to the physician network's treatment of PPO patients, the IPA will provide value to PPO patients as a result of this integration. (This is similar to the scenario described in Statement 8, Example 2 of the Health Care Statements.)

2. Ancillarity.

As set forth in the Health Care Statements, joint negotiations by providers of payer contracts are ancillary to attendant clinical integration if such negotiations are *reasonably necessary* to achieve the integration. Accordingly, in assessing ancillarity, one must consider whether an IPA's joint negotiations of contracts help ensure the overall implementation and delivery of a clinically integrated product. For at least two reasons, such negotiations can serve this purpose.

First, when an IPA requires significant investments in capital and time, joint negotiations of contracts ensure that enough physicians, across multiple specialties, participate in the network to offer a viable, clinically integrated product to payers. Ultimately, IPA member physicians are responsible for the time and expense associated with developing, implementing, and delivering

an integrated product.[14] Like all rational actors, physicians expect to benefit from their time and resource investment in an IPA. An important benefit of their participation in an IPA's network is, typically, delegating at least some payer contracting to the IPA. This saves the physicians the time and hassle of negotiating contracts with payers that choose to contract with the IPA. Even if such negotiations result in better physician terms for some services, it does not necessarily follow that the overall costs of care incurred by payers will increase. Rather, such a result can reflect that payers are more likely to improve contract terms (including price) if they can otherwise reduce costs and enhance quality by (a) improving efficiency and quality through, for instance, clinical care review, credentialing, and quality assurance, and (b) saving transaction costs by negotiating and entering one contract for a network rather than individual physician contracts.

Absent the ability to jointly negotiate contracts, physicians who invest time and money in an IPA will realize literally no benefits from participating in the IPA. The physicians, then, will have every incentive *not* to participate in the IPA's network. Such risk of non-participation in an otherwise legitimate venture has been recognized by the FTC staff (in the context of the *Medsouth* advisory opinion[15]) as well as Commissioner Leary as a reason to allow the joint negotiations of payer contracts:

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[14] Physicians bear the cost of integration in one of two ways: (a) any investment made by the IPA reduces funds allocated to physicians; and/or (b) being charged a fee directly by the IPA.

[15] Letter from Jeffrey W. Brennan, Assistant Director, Health Care Services & Products, FTC, to John J. Miles, Ober, Kaler, Grimes & Shriver (Feb. 19, 2002), available at http://www.ftc.gov/bcadops/medsouth/htm.

> A key finding in the staff [*Medsouth*] opinion is the conclusion that joint contracting was closely related and essential to the success of the venture. This may be true in the sense that neither Medsouth nor other similar associations are likely to embark on such a promising experiment absent [an] assurance they can bargain with payers as a group.[16]

Second, because an IPA can offer payers a single, comprehensive, and integrated network, the network should (if sufficiently integrated) be priced in the aggregate, not through individual contracts with physicians. By developing an integrated network, an IPA will almost certainly seek to offer payers a product that is distinct from and superior to competing products. The procompetitive benefits of an IPA's product (high quality, low cost) are typically achieved only through rigorous analysis and management by IPA employees of the network physicians' delivery of care across the entire health care continuum.[17] The employees will be the most familiar with the benefits stemming from the IPA's integration. These benefits, of course, have value. And this value should be reflected, at least in part, in the terms of IPA contracts. Because IPA employees are in the best position to know the market value of the product offered to payers, they are in the best position to negotiate contract terms that reflect this value.

An argument can always be made that, if an IPA's product is superior to competing products, then payers will price the product at a competitive level irrespective of whether contracts are negotiated individually by physicians or in the aggregate by the IPA. But this argument ignores the realities of contract negotiations. These negotiations involve a process of give and take: they involve an initial offer, counter offers, discussion of terms, justification of positions, etc. Each side seeks to advance its own position. Payers will obviously know the

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[16] Thomas B. Leary, *Health Law Symposium: The Antitrust Implications of "Clinical Integration:" An Analysis of FTC Staff's Advisory Opinion to Medsouth*, 47 St. Louis L. J. 223, 233 (Spring 2003).

[17] This is particularly true with regard to multi-specialty IPAs, which are inherently positioned to manage care across the health care continuum.

value they attribute to the IPA's product; the IPA employees who are responsible for analyzing the network physicians' delivery of care will likewise be in the best position to place a value on the network's services from the IPA's perspective.

Individual physicians, however, who have neither the time nor expertise to assess the aggregate value of a product in which they individually participate, are not in a position to negotiate competitive terms with payers. Payers would have an inherent advantage in any such negotiations, which – as rational actors themselves – they would certainly exploit. While it is always possible, in theory, that any one physician may spend the significant time necessary to assess the aggregate value of an IPA's product, it is a certainty that most of the network physicians would not, as they do not have enough time to perform their normal duties in any event. As a consequence, requiring these physicians to negotiate individual contracts for the integrated network in which they participate would result, in all likelihood, in the IPA's product being undervalued in the market. This, of course, would threaten the viability of the product altogether.

Moreover, it is precisely because of these market realities that the agencies and courts, presumably, apply a "reasonably necessary" standard in assessing ancillarity, as opposed to requiring a much stricter standard such as "absolute necessity." When the sum of a network is greater than its parts, it makes no sense to require that the network be priced on a part-by-part basis. This would create disincentives for participation in the network and risk eliminating the procompetitive efficiencies attendant to the network's product offering. Such a result would be

contrary to a number of court decisions[18] as well as the Charlestown IPA example within Statement 8 of the Health Care Statements.

3. The Relationship Between Integration and Ancillarity.

We believe that the legality of an IPA's joint negotiations cannot be assessed by considering the group's integration separately from the ancillarity requirement. As the ancillarity discussion above suggests, the greater an IPA's investment (in time and capital) in integrating a physician network, the more plausible it is that (1) the physicians would not participate in the network absent the ability to delegate contracting to the IPA and (2) the IPA is offering a valuable product to the market that deserves to be priced in the aggregate. If, for instance, an IPA invests $1,000 a year in distributing HEDIS Statements to physician members – and this is the extent to which the IPA is "integrated" – it is unlikely that this level of integration justifies competing physicians jointly negotiating contract rates. Physicians are not making investments that would likely discourage their participation in the IPA absent the ability to jointly negotiate; and the type of investment made cannot be assumed to lead to the delivery of more efficient or higher quality care. In this context (and others like it), it would be sensible for the FTC to presume that joint negotiations of payer contracts cannot be ancillary to the IPA's integration, as the size of the investment in integration alone could suggest that the IPA is a pretext for competing physicians to seek to raise reimbursement rates through joint negotiations.

On the other hand, if an IPA invests millions of dollars a year to develop clinical protocols, conduct clinical care review, and ensure physician compliance with the protocols, the ancillarity analysis should be much different than that above. First, physicians will not want to

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[18] See e.g., Rothery Storage & Van Co. v. Atlas Van Lines Inc., 792 F.2d 210, 224 (D.C. Cir. 1986); General Leaseways, Inc. v. National Trucking Leasing Assoc., 744 F.2d 588, 595 (7th Cir. 1984).

participate in a process that is expressly designed to regulate the level and type of care they deliver unless the physicians are clearly benefiting from this participation. Delegating contracting responsibilities to an IPA would certainly be a benefit that would foster participation in the IPA. Second, a substantial annual investment – given its size and purpose (regulating care) – has to be assumed, to a certain degree, to offer a valuable product to the market. And because IPA employees are better situated than physicians to assess the value of the product, they are in a better position to negotiate payer contracts that reflect this value. In this context, the IPA's investment can be assumed to justify – at least to a degree – joint negotiation of payer contracts.

This conceptual framework is, we believe, consistent with the purpose of the FTC's recent enforcement actions. Under this framework, sham IPAs would not pass muster, while the conduct of an IPA that has invested significant resources to clinically integrate would be subject to the rule of reason (provided that the level of integration was sufficient under the Health Care Statements). We also believe that this framework is consistent with the purpose of the revisions to the Health Care Statements in 1996, as articulated by William Baer (then the Director of the Bureau of Competition) shortly after the revisions were implemented:

> One overriding theme of the revised statements is that in evaluating both potential efficiencies and competitive effects, we will look at the substance of the arrangement, not just its form. Arrangements designed primarily to impede or prevent competitive forces from operating in the market, rather than to achieve efficiencies, will continue to be condemned summarily. But, where the underlying substance of the arrangement has a plausible efficiency rationale, we will still investigate but under the rule of reason.[19]

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[19] William J. Baer, Current Issues in Health Care Antitrust Enforcement at the Federal Trade Commission, Address Before the American Bar Association (Oct. 24, 1996), at 4 (available at www.ftc.gov).

4 Conclusion.

As the health insurance market experiences growth in PPO products, physician participation in clinically integrated IPAs (to serve this market) is becoming more important. To the extent the FTC agrees that these IPAs can enhance quality and reduce costs, the agency has an institutional interest in promoting physician participation in these ventures.[20] Providing clarity as to the Health Care Statements clinical integration and ancillarity requirements will go a long way towards promoting this participation. CAPG welcomes the opportunity to discuss these issues further with the FTC staff.

[20] As Chairman Muris recently recognized, "because quality is so important in health care, we should err on the side of conduct that promises to improve patient care." Chairman Timothy J. Muris, Everything Old is New Again: Health Care and Competition in the 21st Century, Address Before the 7th Annual Competition Health Care Forum (Nov. 7, 2002), at 18.

ATTACHMENT

AN IPA BASED MODEL FOR CLINICAL INTEGRATION IN A PPO SETTING

By
Bartley Asner, M.D.
California Association of Physician Groups

Introduction

In the PPO arena as it currently functions today, a patient can choose a doctor from an extensive network of contracted primary care and specialist physicians. The individual contracted physician can then proceed to treat that patient, often in a vacuum, with minimal if any coordination of care between responsible physicians. The result of this is episodic, haphazard, duplicative care, and a less favorable outcome for the patient. For example, a patient with a chronic multisystem disease such as diabetes who has associated eye, kidney and heart problems is typically seen by a number of specialists with poor coordination of their efforts. While the primary care physician in theory should be coordinating this care, in the PPO environment, there is no expectation that the patient see a primary care provider. In fact, the patient often self refers to specialists, leading to chaos rather than coordination of care. In addition, in the PPO environment, a physician often admits a patient to the hospital without the knowledge of other physicians who have participated in the outpatient care of that patient. (In fact, the lack of coordinated outpatient care may have itself led to the admission). The exploding costs of pharmaceuticals, high tech procedures and inpatient care, coupled with the increasing patient financial responsibility inherent in consumer directed health care, subject the consumer to significant financial burdens. There is little or no accountability for the delivery of cost effective, quality care in a PPO environment.

The California Independent Practice Association (IPA) model consists of both primary care and specialty physicians in a contractually integrated group under which they agree to provide all appropriate care for HMO patients of the IPA, under the guidelines and coordination of the IPA clinical team. This is a very efficient, cost effective model that has proven to lower costs while delivering quality care. The principles of this cost effective delivery model are applicable to PPO patients, but will require a change in the nature of PPO healthcare delivery. At present, PPO claims are paid directly to providers by a health plan and not to an IPA, precluding the IPA from access to the claims information that it can use for identification of defined patient populations, and retrospective review of physician performance for profiling purposes. Furthermore, since the PPO physician currently has no accountability to an IPA for the care delivered, the potential for over or under utilization, duplication and lack of coordinated care is apparent.

With the approval of the Federal Trade Commission, an IPA, and its physician network, specifically one that is actively engaged in the care of HMO patients, could contract directly with a health plan for PPO business, and provide a more cost effective model. This will require additional IPA resources dedicated to PPO patients in order to provide more intensive oversight of care in both the inpatient and outpatient settings, as is the current model for HMO patients. Although there are administrative and physician costs associated with providing such services, the net effect on overall cost of care will be a reduction in cost growth, and improvement in the quality of care. There is definite value in an IPA utilizing a physician network that is simultaneously providing care for patients under the HMO model ("the spillover effect") in that these physicians are already performing in a cooperative, collaborative and cost effective manner. The importance of this element is such that the FTC could consider this a prerequisite for an IPA to enter into the PPO contracting arena.

HMO vs. PPO

In order to better understand the concepts espoused in this paper, particularly as California IPAs transition to the PPO environment, a basic primer on the economics of health care delivery may be helpful. In the California delegated HMO model, the health plan collects a premium payment from the employer, and in turn transfers a portion of that payment as capitation to the IPA in order to cover the cost of professional services performed by primary care and specialty physicians, and ancillary services such as the technical cost of radiology procedures. In many cases, the IPA is in financial partnership ("shared risk" arrangement) with the health plan to cover the cost of emergency room services, outpatient surgery and inpatient care. The health plan retains a percentage of the premium to cover its administrative costs, marketing, enrollment, and the cost of out of area services and some pharmaceuticals. This relationship is memorialized by a contract that defines the terms of the IPA and health plan relationship, as well as the division of financial responsibility (DOFR). The IPA, in turn, enters into a written contract with each of its physicians (and non physician providers of care), which defines the financial and clinical parameters under which the physician or ancillary service provider delivers care to the IPA patients. Specifically, such a contract defines the clinical care expectations of the IPA, and requires that the physician provide care according to the IPA's policies, procedures and guidelines. The IPA reserves the right to monitor the physician's performance, and require a response to patient grievances and other quality of care issues. The physician submits a claim to the IPA for services rendered, which in turn pays the physician on either a capitated basis for a population of patients, or in some cases, on a fee for service basis. Most importantly, the physician looks to the IPA, not the health plan, for reimbursement, and in turn submits clinical information regarding the patient's care, which drives the payment. In this way, the IPA collects data and information on its patients and on the performance of its physicians, which can be used for profiling, education and comparative benchmarking.

Under the current PPO model, the financial and contracting relationships are quite different from the HMO model described above. Each individual physician signs a PPO

contract directly with multiple health plans, each of which defines the financial terms under which care is rendered to patients of the health plan. While the contract obligates the physician to follow the policies of each health plan, such policies are developed by distant organizations that have no local relationship with the physician. Consequently, there is no local community support for the physician to follow evidence-based guidelines, resulting in great variability of care across the country, and within a local area. Coordination of care is absent. The physician looks directly to the health plan for compensation, and this financial relationship serves as the primary bond between the physician and the plan.

Proposal

As the current American health insurance system includes a large patient population cared for under PPO contracts, it would be advantageous for those patients to avail themselves of the coordinated care model afforded to patients by a well managed IPA in the HMO environment. As a proposed model for the future care of PPO patients, IPA's could focus on clinical integration in the following three areas: 1) Management of inpatient care; 2) Management of chronic disease in outpatient populations; and 3) Implementation of guidelines for appropriate utilization of high tech, high cost procedures. (See Appendix A)

In the proposed non-financially integrated model -- one that employs the principles of coordinated, integrated care -- an IPA can benefit consumers by improving the efficiency in the delivery of care, reducing costs and improving the quality of care. From the clinical perspective, an IPA will provide an organized delivery system that provides the right care at the right time and place for the right patient. While the IPA and its physicians will follow established evidence-based guidelines, the care will be delivered on a local level in a personalized, collaborative framework utilizing an IPA employed medical director and local clinical staff to complement the care of the individual physician. The specific clinical activities to be undertaken by the IPA include quality assurance (credentialing, grievance and appeal monitoring, office audits, and physician profiling), chronic disease and population management (e.g., frequent emergency room utilizers), coordination of inpatient care with guided transition to the outpatient setting and managing the utilization of high cost procedures. In the end, the coordination of care results in efficiency (patients are guided through the complex health care system), lower cost (through utilization management of expensive resources) and improved quality (the correct care).

This plan distinctly differs from what an individual physician can do alone. In the PPO environment, there is no effective quality assurance/improvement mechanism since any given health plan relationship is likely to involve small numbers of patients that are not statistically significant. When an IPA aggregates large numbers of patients across multiple plans, quality improvement analyses and actions have relevance and statistical significance. With regard to coordinating the care of populations of patients, no individual physician has the time or resources to focus on this. An IPA provides

dedicated resources to accomplish coordination of care. With regard to inpatient care, individual physicians focus on the disease at hand, without a focus on coordination of care across multiple disciplines; furthermore, they do not have the time or resources to provide an optimal transition to the outpatient setting (with follow up to insure appointments are made, prescriptions filled and medical equipment delivered to the home).

The goals of physician collaboration can be accomplished in the best interests of patients through a centralized local physician organization, an IPA, that provides organized systems of care. Such a system will invest in information technology, care management nurses, data collection, and management and clinical programs to enhance the care of the patients. Furthermore, the aggregation of large numbers of patients will serve as the basis for comparative physician performance profiling. A significant investment is necessary in a core information system that collects, stores and reports on clinical information by physician, by patient and by diagnostic category. Ideally, the Internet can serve as a real time means of communication between the IPA and its physicians. A significant investment in personnel is required to perform the tasks of an IPA, including a local medical director, care management nurses, data analysts, claims processors, and a information services support department.

How can we be sure that the programs described will in fact be effective? A series of metrics will need to be established to measure and verify ongoing success. These would include cost and utilization statistics, patient satisfaction surveys, physician compliance with care management guidelines, and scores on industry accepted clinical guidelines (Pay for Performance, HEDIS).

What assurance is there that individual physicians will cooperate in these efforts? First and foremost, the health care world has changed and physicians recognize this. No longer can an individual physician do whatever he or she chooses. Studies from the Dartmouth Group (Dr. Wennberg) and others have documented the variability in clinical performance and outcomes across the country, and across regions. This is clearly unacceptable. At the same time, employers are demanding measurable value in response to recent premium increases, and defining quality as they see it. Physicians must respond accordingly and cannot do this as individuals. The culture of the individual physician is eroding. Furthermore, physicians recognize that they cannot keep up with the information demands of their profession, or the Internet-based demands of their patients, and so they need an organization like an IPA to supplement their clinical skills. At the same time, through the IPA, physician performance can be monitored, profiled and compared, with financial payments tied to quality performance measurements. IPAs can align incentives to improve the quality of care in a cost effective manner. Bonuses can be paid for quality. Physician and IPA performance can be measured and reported. No physician can afford to be an outlier! The consequence will be the right care in the right setting at the right cost resulting in efficiency, decreased cost, and increased quality. Is there empirical evidence to support these assertions? California premiums are the lowest in the nation, based primarily on the success of organized medical groups and IPAs. A recent Health Affairs article documents the success of California care management

programs. On a local level, there are anecdotal stories of success in enhancing the care of groups of patients, such as the use of ACE Inhibitors in post myocardial infarction patients.

The likelihood of success for an IPA depends, to an extent, on the size of the group. While there are no set parameters, a critical mass is necessary to afford the investment in technology systems, other infrastructure, care management programs and professional staff. The larger the number of patients cared for under an IPA, the greater the potential for covering these fixed costs, and affording clinical programs which coordinate the care of patient populations. There is an advantage for an IPA to have both primary care physicians and specialists under contract in that the management of certain disease states is dependent on the care and cooperation of specialists.

With the above perspective, it should be apparent that joint and direct contracting by the IPA with health plans is necessary to accomplish the aforementioned clinical goals. The clinical programs require a cooperative effort by an IPA, its clinical staff and its contracted physicians. If the physicians have not contracted with the IPA to care for these PPO patients, there is no clinical commitment, and episodic, uncoordinated care will result. The physician's contract with the IPA gives the IPA the right to manage the care of the patients in collaboration with the physician. Furthermore, the physician will be required to submit claims data on the care being provided to the patients, which will be entered into the IPA information system for managing the care of the patients and profiling the physicians. The IPA contract with the health plan will assure that contract terms are consistent for all its physicians, and provide a funding mechanism to finance the clinical programs. In the end, this process will insure that the physicians, not the health plans, are managing the care of patients, and preserve the value of local clinical care within national guidelines.

Joint pricing is a necessity in this model. Physicians will need to be paid for their services on a consistent fee schedule by specialty to insure broad participation. In addition, the IPA needs to be empowered to vary those payments for quality purposes. It is important that the IPA have a direct financial connection (contract) to its physicians so that they understand the aligned incentives. The IPA serves as the vehicle for equitable physician distribution of the health care dollars.

One master health plan contract is needed which creates, or evolves toward, a revenue model for payments to flow from the health plan to the IPA, and from the IPA to the physician network. A joint health plan contract on behalf of all of its physicians will enable the IPA to fund its infrastructure and programmatic requirements, an essential part of this integrated model.

To accomplish the clinical goals of the IPA, exclusivity with physicians should be permitted. This creates efficiencies for the IPA, the physicians and the patients, which translates into quality care for patients. Ideally, physicians should operate under <u>one</u> set of rules from <u>one</u> organization, and interact with <u>one</u> medical director and nursing staff to foster education and enhance performance. The patient must identify with a physician (or

group of physicians), and the physician(s) with one IPA to create the effective clinical programs that have been described. This includes following both clinical guidelines, and administrative rules. Loyalty and commitment of the physician to the one IPA should not be underestimated as a critical success factor. The aggregation of large numbers of patients enables the IPA to effectively profile practice patterns, and provide significant incentives for quality. Lastly, the IPA needs to make information technology investments in the physician's practice, and cannot justify this for a small number of patients.

In conclusion, through the implementation of an IPA-driven clinical program designed to improve the care and cost effectiveness of hospitalization, focus on specific populations of chronically ill patients, and manage referrals for high cost procedures, an IPA can provide clinical integration in the care of a PPO patient population. Although there is a cost to perform these services, the overall cost of healthcare will decrease through focusing on the true drivers of health care inflation (hospitals, pharmaceuticals and technology). The Federal Trade Commission should strongly consider an endorsement of this plan to enable and empower an IPA to contract with a PPO on behalf of its physicians, and deliver care in a clinically integrated, quality based, cost effective manner.

APPENDIX A
Clinical Integration Example

1. Management of inpatient care.

Inpatient care management is often not integrated with outpatient care, and therefore operates as a silo within the health care delivery system; an inpatient is often managed by one physician or specialist without the knowledge or input of other physicians who have cared for that patient. Furthermore, an individual physician has no understanding of what a typical length of stay should be for a given diagnosis, nor does that physician understand the principles of discharge planning to assure that the patient undergoes a smooth transition to the outpatient setting. In an IPA model, there is a care management team consisting of trained nurses who monitor the progress of a patient's care, measured against industry guidelines, and facilitates and coordinates the patient's transition to the outpatient setting (follow up appointments, prescriptions to be filled, supplies and equipment needed). This provides superior care in a more cost effective manner, lowering the length of stay and readmission rate for many patients. As we move into the future, through the use of Internet connectivity software, all inpatient information could be entered in a common system via the web using a hospital computer, a laptop or a personal digital assistant or other input devices. All clinicians could enter notes about the patient's condition for review by other clinicians involved in the care, or those who have managed the patient in an outpatient setting. Bed days can be tracked by specific diagnosis and level of care, and compared to a national standard such as InterQual, thereby minimizing unnecessary excessive length of stay. All reports and tracking could be done over the web. Discharge planning and follow up care would be coordinated.

2. Management of chronic disease in outpatient populations.

Statistics have shown that 5% of patients enrolled in a health plan generate 60% of medical costs. These patients tend to be those with chronic disease or multiple co-morbidities. Using diabetes as an example, the effective management of a population of patients with this diagnosis can lead to superior care in a more cost effective manner, further enhanced in the future by utilizing the efficiency of the Internet as a communication tool. The primary drivers of cost in a diabetic population are inpatient days, specialty visits and emergency room visits. Having identified diabetic patients through a combination of pharmacy data, claims data and ER and hospital visits, the diabetes patient can then be screened through a clinical assessment questionnaire to determine if there would be a benefit from enrollment in a diabetes population management program, (perhaps utilizing Internet based software.) Focused intervention, and compliance monitoring with diabetic care protocols, would then be undertaken to provide patient education, improve access to appropriate specialty care, and reduce emergency room visits and inpatient stays. The care management protocol would also focus on improving the patient's ability to manage his or her own disease. Through the future use of the Internet, the patient and all physicians involved in the patient's care

could participate actively in the care management process. Diabetes is but one example of a number of common, chronic diseases that would be subject to similar rigorous population management programs to provide cost effective, high quality care. These principles can and will be extended to the care of congestive heart failure, asthma, cancer, hypertension and other disease states as applicable to a given population.

3. Implementation of guidelines for appropriate utilization of high tech, high cost procedures.

Through the process of authorizing (approving) high cost services in real time, an IPA can intervene to assure that a patient receives the correct care in the correct setting at an appropriate cost without duplication of services. As an example, a physician might order a CT scan for a patient not knowing that one had recently been ordered by another physician. Alternatively, there might be a superior test that can be performed, and it would be more cost effective to go directly to that test (e.g. ordering an MRI directly, rather than performing a CT Scan and then an MRI). Other examples of procedures subject to review would include: appropriate indications for bariatric (weight loss) surgery, coronary artery bypass versus less invasive angiography, and the appropriate indications for new technology and pharmaceuticals. As an example, Xolair is a recently approved injectable drug for chronic asthma. Appropriate utilization review insures that mild asthmatics do not unnecessarily receive this expensive drug, while severe asthmatics with frequent emergency room and in patient stays are treated with Xolair. To that end, by requiring authorization of a limited number of high cost procedures, and subjecting this authorization process to evidence based clinical guidelines, patients can receive the best care at the best value. With consumer driven health care raising the patient's share of cost, this will be a direct savings (copay, coinsurance or deductible) for the patient as well. Through the use of the Internet, the authorization procedure can be an efficient process in which a physician receives a near immediate response to most authorization requests over the web. The referral request could be subject to a clinical guideline that would be posted on the web, serving as an educational tool for the physician. This will diminish the variability that exists in medicine today as individual physicians do as they choose in a PPO setting, rather than what has been proven, according to evidence based standards, to be the best care for the patient.