Accountable Care Organizations and Antitrust Conference
Briefing Document

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Abstract

This briefing paper serves as a background for the discussion that will take place during the "Accountable Care Organizations and Antitrust Conference" to be held on November 11, 2011 at UC Berkeley. With the October 20, 2011 release of the final rule creating the Medicare Shared Savings Program (MSSP), the Center for Medicare & Medicaid Services has paved the way for a national move towards coordinated delivery systems known as Accountable Care Organizations (ACOs). This paper provides background on government policy towards an accountable care delivery system, the balance between integration efficiencies and market power, and the goals and methods of antitrust analysis within healthcare delivery. It provides context for the issues of market definition, anticompetitive effects, antitrust evaluations, and contracting practices among healthcare providers. The paper concludes with a brief discussion of the California ban on the corporate practice of medicine.

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Section I: Background

On October 20, 2011, the Center for Medicare & Medicaid Services (CMS) issued its final rules creating the Medicare Shared Savings Program (MSSP). The Patient Protection and Affordable Care Act called on the Secretary of Health and Human Services to create the program to promote a new structure for care delivery known as Accountable Care Organizations (ACOs). ACOs can be viewed as multi-specialty organizations including various providers, hospitals and ambulatory care services that share information about patients, streamline processes, standardize practice, coordinate care, and share in the risk and rewards of managing a population. UC Berkeley School of Public Health Dean Steve Shortell has had significant influence in promoting and guiding policymakers and stakeholders towards the accountable care model (See accompanying resources list for select articles). The goal of the MSSP is to encourage various providers to work together and coordinate care via ACOs, in order to provide higher quality, lower cost health services to Medicare fee for service beneficiaries. A number of private payers have already initiated the formation of their own ACOs, with the goal of bringing innovative care delivery methods to the entire health care market. To make both the public and private efforts more congruent, providers and payers would like to see the creation of ACOs that can serve both commercial and Medicare patients.

The predominant payment mechanism today is fee for service (FFS), in which each health service is charged and paid for independently of others. FFS is often criticized as leading to overutilization of services and fragmented care. The emergence of ACOs is designed to create widespread change in the delivery system while allowing for a gradual shift in reimbursement away from FFS. The expectation is that once delivery systems adapt towards care coordination and population health management, they will be in better position to bear risk from reimbursement mechanisms such as bundled payments. Bundled, or episodic, payments is a reimbursement method in which a single payment is provided for all care

related to a treatment or condition.[1] In such a payment system, providers are responsible for managing the entire care process of the treatment, and they carry the risk for any preventable complications.[2] While policymakers recognize the benefits of enhanced care coordination, they are also concerned that creating large provider groups that jointly negotiate prices may lead to significant market leverage for ACOs and reduced competition in provider markets. As such, the Federal Trade Commission (FTC) and Department of Justice (DOJ), the "Agencies," issued an accompanying Policy Statement on Antitrust Enforcement for Accountable Care Organizations alongside the CMS regulations. This is still a very malleable policy environment where both health care policymakers and antitrust authorities are striving to find the right mixture between both the potential efficiency gains and potential market power issues inherent to this legislation.

Under the MSSP rule, an ACO is a legal entity in which physician networks, group practices, individual physicians, hospital, ambulatory service centers, rural or federally qualified health centers may participate. The ACO rules include the following required criteria for clinical integration and leadership:[3]

- Formation via a legal structure that allows the ACO to receive and distribute shared savings
- Use of leadership and management structure that includes clinical and administrative processes
- Promotion of evidence-based medical practice or clinical guidelines
- Promotion of patient engagement in care
- Internal reporting on quality and cost metrics
- Care coordination via telehealth, remote patient monitoring or other technologies
- Utilization of patient-centered care processes

Potential Efficiencies: As Gail Wilensky highlights in "Lessons from the Physician Group Practice Demonstration —A Sobering Reflection," the effect that ACOs will have on the delivery system is still uncertain. Between 2005 – 2008, CMS tested the ACO-type model via a Physician Group Practice

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[1] Shortell & Casalino, *Accountable Care Systems For Comprehensive Health Care Reform*, Robert Wood Johnson Foundation, Mar 2, 2007

[2] Merlis, *Accountable Care Organizations*, Health Affairs, Jul 2010

[3] CMS, *Medicare Shared Savings Program Final Rule*, Oct 2011

demonstration project that included ten large multi-specialty groups with a history of efforts in care coordination. The results of the demonstration were mixed. The groups performed quite well on the 32 quality measures utilized; however, only half of the organizations were able to achieve the 2% savings goal in the third year and only two achieved this level of savings in the first year. Various design issues that have been addressed in the MSSP rule, however, may have contributed to the disappointing savings results.[4]

At the state level, commercial insurers have been eager to experiment via a number of ongoing ACO pilots that are independent of the MSSP. In 2010, Blue Shield began a two-year ACO program with Catholic Healthcare West and Hill Physicians that covers 41,000 CalPERS members. Preliminary results of this program show a 14% reduction in total patient days in a facility, 17% reduction in patient readmissions, and estimated savings of $15.5 million. In March, 2011 Anthem Blue Cross, Health Care Partners, and Monarch HealthCare announced an ACO for PPO patients in Southern California. Furthermore, the Accountable Care Network, a safety net effort in Los Angeles, is launching an ACO-like program that creates risk pools between hospitals and community clinic providers. [5]

Most organizations implementing ACOs recognize that payment reform is an integral part of creating successful care coordination. Commercial ACOs to date have taken incremental steps at implementing new payment mechanisms, recognizing that most providers are not yet at the point where they are willing and able to manage financial risk from global payments. Some payment mechanisms utilized in current ACO projects include: 1) incentives for hitting quality and cost targets 2) care management fee per member per month based on quality and cost goals 3) shared savings with or without shared loss contingent upon quality thresholds.[6] In some contracts, the weighting on FFS reimbursement is gradually diminished over time, allowing for more reimbursement to be tied to quality and cost targets.

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[4]Wilensky, *Lessons from the Physician Group Practice Demonstration —A Sobering Reflection,* New England Journal of Medicine, Sept 2011
[5] CA Healthcare Foundation, *Accountable Care Organizations in California: Programmatic and Legal Considerations*; Jul 2011
[6] Higgins, et al, *Early Lessons From Accountable Care Models In The Private Sector: Partnerships Between Health Plans And Providers*, Health Affairs, Sept 2011

Market Power: While some commercial payers have been proactive in propelling ACOs, they share concerns about possible unintended consequences of such organizations. Prices in the medical provider market are determined by bilateral bargaining between individual insurers and providers, with contracted prices for services often being unique to the negotiation. Thus, antitrust authorities worry that collaborating providers may gain market power in negotiating with health care plans, and increase prices against a subset of commercial insurers even if they cannot do so against Medicare or other commercial insurers. Price increases are further facilitated by the fact that they are ultimately diffused to a multitude of employers and employees through premiums and deductibles.[7] The importance of competition in healthcare provision is highlighted via a 2010 study by the Attorney General of Massachusetts, which assessed causes of price variations in healthcare services. The report concluded that there is great price variation for health services within geographic areas and that:

> "Price variations are not correlated to (1) quality of care, (2) the sickness of the population served or complexity of the services provided, (3) the extent to which a provider cares for a large portion of patients on Medicare or Medicaid, or (4) whether a provider is an academic teaching or research facility. Moreover, (5) price variations are not adequately explained by differences in hospital costs of delivering similar services at similar facilities." [8]

Rather, the Massachusetts AG found that price differences *are* correlated to market leverage of the hospital or provider, and that increases in healthcare costs are mainly explained by increased prices rather than utilization. Similarly, a 2010 California study found that hospitals and physicians significantly increased their bargaining leverage when negotiating together via hospital systems, medical groups, or independent physician associations (IPAs).[9] Reimbursement differences among providers are substantial and much of the variation stems from negotiating clout derived from ranging market shares.[10]

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[7] Varanini, ACO Legal Principles, CA Attorney General's Office, Oct 2011

[8] Massachusetts Attorney General's Office, *Examination of Health Care Cost Trends and Cost Drivers*, Mar 2010

[9] Berenson, et al, *Unchecked Provider Clout in California Foreshadows Challenges to Health Reform*; Apr 2010

[10] Massachusetts Attorney General's Office, *Examination of Health Care Cost Trends and Cost Drivers*, Mar 2010

In general provider markets have been an important area of antitrust enforcement efforts, with over thirty hospital mergers litigated and a number of others settled.[11] Between 1990 – 2003, there was a nationwide wave of hospital mergers, with a reduction from six to four local hospital competitors in the average metropolitan area.[12] Antitrust authorities have also targeted Physician-Hospital Organizations and hospital networks where they believed anticompetitive behavior may have occurred. Antitrust officials generally believe that successful health plan competition requires competition in provider markets, and maintaining such competition has been integral to antitrust strategy. Greaney argues that a central objective of antitrust policy is to pomote efficient organizational structures and agreements that can increase consumer welfare via higher quality and lower costs.[13]

Efficiency vs. Market Power: The CMS rules around clinical integration and the corresponding Antitrust Policy Statement are designed to encourage efficiency-creating provider collaborations and strike a balance between ensuring both coordination and competition. The rules and Antitrust Policy Statement build off of the Statements of Antitrust Enforcement Policy in Health Care issued by the Agencies in 1996. In these statements, the FTC and DOJ delineated a framework for evaluating collaborations among healthcare organizations. The framework states that, on their own, joint price negotiations by competing, non-integrated providers are inherently illegal collusion. However, the 1996 Statements allow some joint price negotiations that are reasonably related and necessary for efficiency-improving integration. Such situations are analyzed under the "Rule of Reason", which weighs the procompetitive versus anticompetitive effects of such collaboration.[14] According to the 1996 guidelines, organizations may implement either clinical or financial integration as tools to lower costs and improve quality. Sharing financial risk must be reasonably likely to lead to clinical integration, which is expected to create the

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[11] Greaney, *Competition Policy and Organizational Fragmentation in Health Care*, University of Pittsburgh Law Review, 2009

[12] Vogt & Town, *How has Hospital Consolidation affected the Price and Quality of Care,* Robert Wood Johnson Foundation; Feb 2006

[13] Greaney, *Competition Policy and Organizational Fragmentation in Health Care*, University of Pittsburgh Law Review, 2009

[14] FTC, *Advisory opinion regarding MedSouth IPA collaboration*, Feb 2002

coordination to ultimately reduce costs and improve quality.[15] The ACO Antitrust Policy Statement complements the 1996 statements by stating that an ACO must meet CMS eligibility criteria around clinical integration in order to fall under the "Rule of Reason" analysis that allows some joint price negotiations. In order to be afforded this benefit of the doubt, an ACO must use the same governance, leadership and clinical / administrative processes in the commercial market as it uses for the MSSP. On the California state level, providers are allowed to form contracting units or jointly negotiate alternate rates with insurers with an initial presumption that such activities are legal. However this assumption can be rebutted in various ways, such as by showing that a collaboration has market power or has no plausible efficiencies. Furthermore, not only is federal law independent of state law but also the California Attorney General has the power to enforce federal, as well as state law. Thus, both the California Attorney General's Office and federal antitrust enforcers have enforcement authority regarding ACOs.[16]

The goal of current ACO efforts by the CMS and commercial payers, along with antitrust vigiliance in this area, is to promote both efficient and competitive delivery of healthcare. The following pages will descibe the salient economic and legal issues around antitrust that arise from the formation of ACOs, as well as how those issues manifest themselves in the Antitrust Policy Statement (articulated at the beginning of each section in a text box)[17]. Much of the economics and legal literature referenced is based on effects of hospital mergers, as this is the greatest source of analysis available on effects of integration within healthcare.

Section II: Market Definition

> The Antitrust Policy Statement asks ACOs to calculate a "Primary Service Area" (PSA), which is the lowest number of contiguous zip codes from which a provider derives 75% of its patients. ACOs are encouraged to evaluate the PSA market shares of independent ACO participants (e.g. hospitals, physician group practices, etc.) that provide a "common service" (based on Medicare Specialty Code for physicians, Major Diagnostic Categories for hospital services, or Outpatient Categories). The market share within a PSA is used as a basic screening tool to allow ACOs to identify those organizations which may pose the largest antitrust risk.

[15] FTC & DOJ, *Statements of Antitrust Enforcement Policy in Health Care,* 1996
[16] Varanini, ACO Legal Principles, CA Attorney General's Office, Oct 2011

While there are other ways to demonstrate anticompetitive effects, market definition and share is a commonly utilized mechanism to demonstrate market power within a specific product and geographic area. Healthcare product markets generally consist of specific services, such as cardiac or orthopedic care, and the definition of such has not generally been particularly contentious in merger litigation.[18] In the case of the MSPP PSA calculations, product markets are based on Medicare Specialty Codes, Major Diagnostic Categories, or Outpatient Categories. CMS will provide a list of applicable services, as well provide Medicare data for calculating PSA shares in cases where state all-payer data is not available.[19] The following section, titled "The Negative Effects of Provider Power" describes the potential anticompetitive effects resulting from high provider market share.

In contrast to product markets, there has been significant controversy around how to best define geographic markets. The Antitrust Policy Statement utilizes the Primary Service Areas as a simple tool to 1) determine the relevant geographic market in which the ACO competes and 2) screen out those ACOs with low market shares that are unlikely to pose antitrust risk. This mechanism allows for an ex ante review of ACOs, assessing the potential for anticompetitive effects prior to the ACO's operation. While the PSA screening mechanism may be useful for a quick determination of "safety zone" organizations, a more in depth market definition and antitrust analysis may be necessary for a number of ACOs.

In determining the relevant geographic market, The FTC and DOJ's merger and hospital-specific guidelines propose the use of the SSNIP test, which assesses whether a merger could result in a "small but significant non-transitory increase in prices". Using this methodology, one starts with a narrowly defined market and tests whether the hospitals in this market, acting as a joint monopolist, could successfully implement a SSNIP. If so, they are the relevant market players. If not, the market definition should be expanded to include the next closest competitor, and the potential for a SSNIP tested again. This iterative process continues until the chosen competitors are able to implement a SSNIP. The SSNIP test is

[18]Gaynor, et al. *A Structural Approach to Market Definition With an Application to the Hospital Industry,* National Bureau of Economic Research, Jan 11
[19]FTC & DOJ, *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program,* Oct 2011

accepted in courts as best defining relevant antitrust markets, however, it is generally impossible to implement as a formula. Doing so would require knowledge of the full demand system of all hospitals, which is effectively impossible to estimate statistically and which would require data on proprietary negotiated prices by insurers as well as prices incurred by patients. In practice, the SSNIP test functions as a very useful thought experiment and framework for organizing evidence. However, it is not possible to use it in a formulaic, dispositive manner.

Given that the SSNIP test it difficult to use in practice, there have been efforts to identify other methods for antitrust analysis. The Elzinga and Hogarty approach has frequently been used in merger review. It is based on patient flows – i.e. calculating what percent of patients currently travel to distant hospitals. If a sizeable number of patients travel to further hospitals to obtain treatment prior to a merger, the assumption is that a price increase following a merger would be unsuccessful as an even greater number of patients would then travel. Elzinga and Hogarty utilizes two criteria: “little out from the inside”, LOFI, (patients going outside the proposed market) and “little in from the outside", LIFO, (patients from outside the proposed market who enter it for care). Generally, a certain maximum threshold for both LOFI and LIFO, such as 10%, is used to defend a market definition.

Elzinga and Hogarty assume that the market is broader than the local hospitals and that a merged entity could not profitably increases prices if there are already significant patient outflows prior to a merger. This approach has achieved jurisdictional precedent, with a number of cases decided in this manner. It is also relatively easy to obtain the necessary data, as it uses available patient-level hospital data that is already collected. The reliance on patient flow (LOFI and LIFO) for antitrust merger analysis means that courts approve hospital consolidations in most cases, because such a method leads to very large markets due to the fact that some patients seek care in distant hospitals for idiosyncratic reasons.[20] Dranove supports this conclusion, suggesting that even in cases with over 30% patient outflow, mergers

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[20]Gaynor, et al. *A Structural Approach to Market Definition With an Application to the Hospital Industry,* National Bureau of Economic Research, Jan 11

can lead to price increases of greater than 10%.[21] Frech, Langenfeld and McCluer conducted a major study of the implications of the Elzinga-Hogarty analysis using actual data from the Sutter-Alta Bates merger. They found that different implementations led to widely varying market definitions ranging from a twelve-by-three-mile area in the East Bay to a 600-by-200 mile area including the large population centers of Northern California. They conclude that patient flow information is useful, but should not be taken as dispositive in some sort of bright-line analysis.[22]

In the *Evanston* hospital merger case, the FTC utilized the testimony of Professor Elzinga himself that his test should not be applied because of two related problems, which he termed the "silent majority fallacy" and the "payer problem." Elzinga defined the "silent majority fallacy" as the fallacy that patients who travel to a distant hospital to obtain care significantly constrain the prices that the closer hospitals charge to patients who will not travel that far. He suggested that the choice of hospitals by patients was not largely based on price but rather was based on location and the preferences of the physician. Elzinga defined the "payer" problem as the problem that patients rarely pay the full cost of patient services directly, thus increasing their insensitivity to price. In the view of the FTC, this did not mean that patient flow data itself was completely irrelevant, but rather should be seen as a very rough benchmark compared against other types of evidence.[23]

There are a number of other methods that antitrust authorities use to define healthcare markets. Metropolitan Statistical Areas (MSAs), which are areas of high population density and tight economic links, are one natural proxy while County lines are another. While MSAs and counties may be useful to describe overall trends, they are rarely valuable for antitrust analysis. Given the local nature of healthcare, the relevant market is often both smaller, and may be more highly concentrated, than that of the MSA. The "fixed-radius" method defines a hospital's market as everything within a certain distance from the hospital; however this approach does not take into account that hospitals often face very

[21]Capps, et al, *Antitrust Policy and Hospital Mergers: Recommendations for a New Approach*, The Antitrust Bulletin, 2002
[22] Frech et al., *Elzinga-Hogarty Tests and Alternative Approaches for Market Share Calculations in Hospital Markets*," Antitrust Law Journal, 2004
[23] Varanini, ACO Legal Principles, CA Attorney General's Office, Oct 2011

differently sized geographic markets. The PSA approach used in the Antitrust Policy Statement is a version of the "variable radius" approach, which defines a market as the minimum size necessary to include a certain percentage of the hospital's patients (in the case of the PSA, 75%).[24]

While most hospital merger cases have utilized patient flow analyses such as Elzinga and Hogarty, studies suggest that these methods overstate the relevant geographic markets for hospitals. They often suggest a much more elastic market than actually exists based on modeling of expected patients and hospital behavior via a SSNIP analysis.[25] The use of PSAs, however, may be helpful as a rough screen to help Agencies focus on those ACOs, especially at the time of formation, which present the greatest anti-competitive concerns. Once they have identified the higher-risk ACOs, antitrust authorities are expected to utilize much more sophisticated market definition tools to assess true antitrust threats. In particular, the perspective of payers on such ACOs are especially useful.

There has been much more analysis of hospital markets than of physician markets. The general perspective is that the market for physician services is smaller than that of hospital services. In the only fully litigated case where a physician IPA was convicted of price-fixing, it was clear that for most specialties, the relevant market was no larger than Tarrant County, Texas (which contains Fort Worth) and is about 9 miles by 10 miles.[26]

Section III: The Negative Effects of Provider Power

To fall within the "Antitrust Safety Zone" ACOs must have a combined share of 30% or less of each "common service" in each participant's PSA for that service. The "Rural Exception" allows ACOs to include one physician or group practice per specialty from each rural area on a non-exclusive basis even if it exceeds the 30% PSA share. The "Dominant Participation Limitation" allows an ACO to fall in the "safety zone" even if has a participant with a great than 50% PSA share as long as no other ACO participant offers that service and the participant is non-exclusive to the ACO. Absent an extraordinary situation, the Agencies will not challenge ACOs that fall within the Safety Zone.

[24] Kessler & McClellan, *Designing Hospital Antitrust Policy to Promote Social Welfare,* National Bureau of Economic Research, Jan 1999

[25] Gaynor, et al. *A Structural Approach to Market Definition With an Application to the Hospital Industry,* National Bureau of Economic Research, Jan 11

[26] *North Texas Specialty Physicians v. FTC*, 528 F. 3d 346 - Court of Appeals 5th Circuit, 2008

While federal antitrust authorities suggest that organizations use PSAs to assess their antitrust risk and perhaps seek voluntary review, they have abandoned the requirement previously set out in their draft antitrust guidelines that ACOs above a certain market share must be reviewed before inception. Federal law does not otherwise require such review before inception with the notable exception of mergers that are above a certain size. Antitrust authorities can initiate their own review of an ACO prior to inception or during its operation, and will have the data necessary from CMS to calculate an ACO's PSA shares as well as to review an ACO's allowable charges and FFS payments.[27]

Antitrust authorities are expected to monitor those ACOs that fall outside the "safety zone" for evidence of market power and anticompetitive effects. The Herfindahl-Hirschman Index (HHI) is used to assess market concentration in antitrust analyses across many industries. The HHI is calculated as the sum of the square of the market share of all competing firms in a market (e.g.: four firms each with 25% market share: HHI = $[(25)^2 + (25)^2 + (25)^2 + (25)^2 = 2{,}500]$). High concentration markets are defined by the DOJ and FTC as those with an HHI index greater than 2500. By this definition, 80% of Metropolitan Statistical Areas are highly concentrated hospital markets and the average hospital HHI for MSAs nationwide increased by 500 points between 1997 and 2009.[28] Antitrust authorities frequently look to understand the merger's impact on HHI, while weighing other factors such as proposed efficiency gains or avoidance of facility closure.[29]

Regardless of HHI, however, Greaney articulates that collaborations or mergers of "must-have" providers or hospitals may create anticompetitive effects even if there are significant other competitors in the market.[30] One way to interpret Greaney's view is that the product market definition should be limited to "must have hospitals." A "must-have" provider is one that insurers are compelled to include in their network, as many consumers would refuse to purchase an insurance plan that did not include that

[27]Varanini, *ACO Legal Principles,* CA Attorney General's Office, Oct 2011
[28]Capps & Dranove, *Market Concentration of Hospitals*, Bates White Economic Consulting, Jun 2011
[29]Kessler & McClellan, *Designing Hospital Antitrust Policy to Promote Social Welfare,* National Bureau of Economic Research, Jan 1999
[30] Greaney, *Competition Policy and Organizational Fragmentation in Health Care*, University of Pittsburgh Law Review, 2009

provider. Such providers often recognize their "must-have" status and utilize it for negotiating leverage with insurers. A number of factors contribute to a provider or hospital being considered as "must-have" within a health plan's network, including its reputation and specialized service offerings.

In Dranove's option-demand model, managed care organizations (MCOs) calculate the importance of a hospital or provider to their network. They determine the increased "Willingness to Pay" (WTP) of consumers for the MCO due to the inclusion of a particular provider or hospital. Thus, when consumers view two different providers as good substitutes, neither provider will have significant leverage over the MCO. However, if there is consolidation among these providers, then consumers no longer have two separate options and their WTP for access to the combined entity will be significant. In order for MCOs to be attractive to consumers, they need to have a large enough pool of providers within their network. To have negotiating leverage with providers then, insurers need to have confidence that there are reasonable substitute providers available for their members in order to be able to credibly threaten exclusion from their network.[31]

Three main approaches are generally utilized to study hospital price competition: the Structure-Conduct-Performance (SCP) approach (looks at association between hospital prices and market concentration), the Event approach (looks at effects from actual mergers that have happened) and the Simulation approach (looks at demand, costs and market power in a specific market and simulates the effect of a merger). A Robert Wood Johnson meta-analysis concludes that almost all studies on hospital mergers demonstrate a resulting price increase. These increases range from 4 -5% for SCP studies, 10 – 40% for Event studies and 5 – 53%, depending on market concentration, for Simulation studies.

Similarly, work by the National Bureau of Economic Research on 1990s hospital mergers indicates that the mergers' aggregate impact contributed to a 3.3% increase in HMO premiums and an overall loss to consumer welfare of $42 billion between 1990 - 2001. The study concludes that the vast majority of consumer welfare was captured by providers, with very little overall welfare loss. Nevertheless the welfare shift is estimated to have led to a loss in private health insurance coverage for

[31]Dranove, et al, *Competition and market power in option demand markets,* RAND Journal of Economics, 2003

almost 700,000 people.[32] Furthermore, courts have not generally been persuaded that the mere fact that merging providers are non-profits means that the merged entity will not raise prices.[33]

Aside from price effects, it is important to understand the impact on hospital costs and quality due to mergers. While prices may have increased due to consolidation, the RWJ meta-analysis suggests slower increase in cost growth post-merger relative to control hospitals. Dranove and Lindrooth's study of 122 mergers found that those mergers which involved actual facilities consolidation demonstrated cost savings of about 14%, while those in which facilities continued to operate separately experienced no significant cost savings.[34] The RWJ meta-analysis does not, however, discuss the causes behind the cost savings nor describe who ultimately benefited from the savings.

The RWJ meta-analysis included 11 studies looking at the effect of hospital mergers on quality. Three studies found that mergers reduced quality, two found that mergers increased quality, two found mixed results based on insurance type or procedure and four showed no effect. This analysis includes the 1988 Shortell study that found increasing concentration had no overall effect on quality for 16 aggregated procedures, as well as the 2002 Gowrisankaran study that found increasing concentration had a negative effect on quality for HMO patients but a positive effect on quality for Medicare patients. However, there has been much less work done to evaluate merger impact on quality than on price, and the conclusions on quality are dependent on specific procedures analyzed. Exercise of market share can potentially lead to decreased quality as much as increased price, but the Agencies have yet to meaningfully address inclusion of quality in antitrust analysis.[35]

Provider concentration has an impact aside from increased provider leverage in negotiations and higher prices. It can also curb efforts for insurance companies to legally remove providers from their networks or to effectively increase consumer involvement in healthcare purchasing. Specifically,

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[32]Town, et al, *The Welfare Consequences of Hospital Mergers*, National Bureau of Economic Research, May 2006
[33] Capps, et al, *Antitrust Policy and Hospital Mergers: Recommendations for a New Approach*, The Antitrust Bulletin, 2002
[34] Vogt &Town, *How has Hospital Consolidation affected the Price and Quality of Care*, Robert Wood Johnson Foundation, Feb 2006
[35] Scheffler & Schneider, *Health care and antitrust: current and future issues for the United States*, Gaceta Sanitaria, 2006

California law requires that insurance companies obtain prior approval from the Department of Managed Care in order to terminate a provider contract and transfer patients to other network providers. In the past, some providers have successfully convinced the Department that adequate substitutes were not available, thus forcing insurance companies to contract with that provider.[36] On the consumer side, analysis of the 2007 New Hampshire Health Cost program, designed to provide patients with price transparency around medical procedures, indicates that the program has not decreased price variation. Weak provider competition, and thus lack of alternative options, is one main explanation for this finding.[37]

California has seen a wave of consolidation in the hospital market since the 1990s, with Sutter Health and Catholic Healthcare West actively acquiring other hospitals. Berenson, Ginsburg and Kemper argue that some hospital systems may be negotiating on an "all or none" basis, forcing plans to include all hospitals in their network at the higher rates. By negotiating holistically, such systems are able to take advantage of several "must-have" hospitals in its system to obtain higher rates for non-must-have hospitals.[38] Berenson, et al, also suggest that insurance companies have felt forced to negotiate with Brown and Toland and Hill Physicians, two Independent Physician Associations with thousands of doctors, in order to have a broad enough network. A physician group medical director indicated that physicians shifting from practicing on their own to joining a physician network are often able to double their rates. In response to the growth in IPAs, plans have actually been shifting patients from HMOs to PPOs to avoid HMO contracts that require negotiating with large physician groups. One health plan executive suggested that HMO plans are the least profitable for insurers because physician groups capitalize on their value and leverage in offering capitated programs (in which providers carry financial risk and are paid a fixed per patient fee that covers all care). Given that PPOs allow greater use of

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[36]Blue Shield, *Comments Relating to Workshop Regarding Accountable Care Organizations*, Nov 2010
[37] Tu & Lauer, *Impact of Health Care Price Transparency on Price Variation: The New Hampshire Experience*; Center for Studying Health System Change, Nov 2009
[38] *Unchecked Provider Clout in California Foreshadows Challenges to Health Reform*;; 04/10

independent physicians who lack the leverage on price negotiations, health plans have been increasingly seeing the PPO product as more profitable.[39]

However, it is important to note that provider leverage is not always expended in negotiations. Some California provider groups are cautious and recognize that if prices increase too much, employer-based insurance in their areas will become unsustainable and plans will move away from HMOs and towards PPOs that take advantage of fragmentation among providers. They also cite Kaiser as offering a moderating presence, as extreme price increases may drive patients and employers towards Kaiser.[40] Increased provider concentration, with its attending anticompetitive effects, renders the potential dangers associated with ACOs more acute. In particular, the formation of ACOs may result in less competition in an area simply because provider concentration issues of the types described above leave Californians with less competitive alternatives to begin with. How and to what extent this needs to be factored into an evaluation of ACOs remains to be determined.

Section IV: Antitrust Evaluations

ACOs can voluntarily seek expedited federal review, based on Rule of Reason analysis, in order to gain further certainty as to application of antitrust laws in their case.

Antitrust authorities and payers generally believe that meaningful financial and clinical integration for ACOs operating in the commercial space must be in place for organizations wishing to avoid antitrust concerns.[41] In granting a voluntary review to ACOs regarding their potential to incur antitrust risk, the Agencies may follow a similar perspective as provided in the MedSouth IPA advisory opinion (2002). In this case, MedSouth wished to institute a program to partially integrate clinical practices and simultaneously negotiate contracts for the services offered by the IPA. The opinion states that the FTC would assess the below areas to weigh the procompetitive versus anticompetitive effects:

[39] Berenson, et al, *Unchecked Provider Clout in California Foreshadows Challenges to Health Reform*; Apr 2010
[40] ibid
[41] Blue Shield, *Comments Relating to Workshop Regarding Accountable Care Organizations*, Nov 2010

- Integration efficiencies: Has there been implementation of protocols and benchmarks that physicians agree to abide by; efficiency goals and concrete plans to achieve them; computer system to assist in implementation of protocols and to share patient information?
- Need for joint contracting: Is it used as a tool to ensure continued physician participation in program and ensure incentives for physician investment of time and effort?
- Market power analysis: Once physician participation is solidified, what is the market share of particular services in certain local geographies?
- Practices to ensure competition: If there is a larger market share, is there both policy and practice of "non-exclusivity" with regards to physicians contracting with payers outside of network at competitive rates?[42]

In terms of antitrust evaluations, several structural elements may be reviewed prior to the full operation of an ACO to determine its anti- and pro- competitive potential. These elements may include: 1) the market power of the ACO's members, 2) the must-have nature of certain providers, 3) proposed restraints on the ACO's members (see section below), and 4) prior anti-competitive conduct of ACO participants. Two other important factors to assess include the flexibility of insurance companies within the target market and the intended use of risk-sharing contracts. Namely, the presence and sensitivity of managed care plans in an area impacts the prices hospitals can charge. Managed Care Organizations in California have been constrained by consumer demands towards open, unrestricted networks, legal requirements limiting their ability to drop providers from networks, and contracting clauses that prohibiting them from directing patients towards higher-value providers. While, Dranove suggests that MCOs continue to leverage the existence of competitive hospitals against each other in California, they are less effective at doing so than they were in the early 1990s when they had greater flexibility in

[42]FTC, *Advisory opinion regarding MedSouth IPA collaboration* , Feb 2002

managing network restrictions.[43] Thus the level of flexibility and control wielded by insurance companies may be a key determinant in antitrust evaluations.

The expected bearing of financial risk likely or presumed to lead to clinical integration may also pre-emptively demonstrate that a commercial ACO is motivated by greater coordination rather than market power. A study that analyzed physician integration in four different markets looked towards acceptance of risk contracts and usage of utilization and clinical management tools as evidence of a move towards efficiency gains. Where such actions were not seen, physician integration was hypothesized as a move mainly motivated by increased market power. In particular, the combination of downward pressure on insurance premiums and weak hospital systems in the LA / Orange County area allows physicians to profitably accept capitated payments and invest in the clinical management tools to do so successfully. In areas where hospital power was strong or there was little downward pressure on premiums, there was less success or impetus to move towards capitated delivery systems.[44] Of course, information signaling intent is only one part of the evidence that must be examined in order to see if a contractual practice or organization is anticompetitive or not. Furthermore, there has been a trend among regulatory agencies to encourage clinical versus financial integration goals. For example, the final MSPP rule does not specify how or to whom shared savings must accrue, and instead focuses on implementation of specific clinical objectives. Whereas ACOs in the MSSP already are subject to rigorous clinical integration criteria, no such criteria exist for commercial ACOs.

Once an ACO is in operation, antitrust authorities can monitor it for effect on costs, prices, and quality, weigh the procompetitive and anticompetitive effects, and take *ex post facto* action against the ACO. CMS' collection of quality data for its Medicare beneficiaries, as well as a new California law (SB 751 passed 9/6/11; discussed further in Section V below) that prevents providers from barring the release of quality and cost information by insurers, may facilitate increased monitoring of ACO effects on care

[43] Dranove, et al. *Is the impact of managed care on hospital prices decreasing?,* Journal of Health Economics, Jan 2008

[44] Rosenthal, et al. *Managed Care and Market Power: Physician Organizations in Four Markets,* Health Affairs; Oct 2011

quality. The authorities could also consider the nature and outcomes of negotiations between providers and commercial payers; for example, the 2001 demands from Sutter Health and Adventist Health to cancel their contracts with Blue Cross if the systems did not receive the 20 – 30% increase they were seeking.[45]

The cases of the Alta Bates – Summit and Evanston mergers demonstrate efforts by the Agencies to monitor the effects of a merger. An after-the-fact FTC analysis of Sutter's Alta Bates – Summit merger suggests that the transaction was anticompetitive. In this case, the FTC's evaluation of commercial claims data from the two hospitals indicated that Summit's price increase following the merger was one of the highest of any comparable California hospital. However, the merger's effect on quality was not evaluated in this study, and it is important to note that there was concern that if Sutter did not purchase Summit, the hospital's poor situation may have led it to completely exit the market instead.[46] In the Evanston case, the consummated acquisition of Highland Park Hospital by Evanston Northwestern Healthcare Corp was found to be anticompetitive. Following the Evanston merger, four of the five commercial insurers were forced to raise their prices by at least ten percentage points more at the merged hospital relative to other Chicago area hospitals. One insurer experienced a relative price increase in excess of 50 percentage points. These results were highly robust to different control groups and case-mix adjustment methods. [47]

Following this ruling, the hospitals were ordered to restore competition via separate price negotiations. In obtaining the ruling, the FTC defined the relevant geographical market as a small triangle in which only three hospitals were located (two of whom were involved in the merger). The FTC also utilized evidence showing that actual fee increases by the merging entities were not attributable to anything other than the entities' increased power in the market.[48]

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[45] Capps, et al, *Antitrust Policy and Hospital Mergers: Recommendations for a New Approach*, The Antitrust Bulletin, 2002

[46]Tenn, *The Price Effects of Hospital Mergers: A Case Study of the Sutter-Summit Transaction,* FTC; Nov 2008

[47] Haas-Wilson & Garmon, *Hospital Mergers and Competitive Effects: Two Retrospective Analyses*, International Journal of Business Economics, Feb 2011

[48] Varanini, ACO Legal Principles, CA Attorney General's Office, Oct 2011

The costs borne by providers may offer evidence as to whether efficiency goals are being met for purposes of an *ex post* review of ACOs. A study on a various group incentives programs between hospitals and cardiologists suggests that gain-sharing arrangements led to a decrease in supply costs for stents, both due to a reduction in quantity but mainly through a reduction in price. Group incentives led to substitution towards less expensive product types, some standardization in products used, and increased bargaining and contract compliance discounts with manufacturers. More costly groups saw the greatest reduction in spending, and the effect was seen across various sizes and heterogeneity of physician groups.[49] Indeed, the new final ACO rules from CMS stress the need to use evidence-based procedures and coordination of care, supported by IT integration, to reduce costs.

Furthermore, how quickly competitors reposition themselves to take advantage of higher prices charged by an ACO may factor into antitrust analysis. If the formation of an ACO were to be analogized to merger policies, then ACOs would need to show that entry would be likely within a two-year period to offset any anti-competitive effects. If an ACO has been in operation, and charging higher fees for a two-year period or longer, then courts can look to actual activity in the market to judge new entry issues.[50]

Section V: Exclusivity & contracting practices

All hospitals or ambulatory surgery centers must be non-exclusive to an ACO, regardless of PSA share. Furthermore, to remain in the "safety zone" and qualify for the rural provider exception or for a dominant provider limitation, such providers must be non-exclusive to the ACO. ACOs outside of the safety zone should avoid contracting with any participant on an exclusive basis – either implicitly or explicitly. All ACOs should avoid sharing pricing or other competitive data with provider participants. ACOs outside of the safety zone should avoid contracting practices that: limit the ability of plans to steer patients towards certain providers or create tiered products; prevent plans from sharing cost or quality data with their members; or require plans to purchase services from affiliate providers outside the ACO.

While an ACO could be found to be legal in a rule of reason analysis, conduct committed by it, such as exclusivity contracts with its members, tying of services, or inappropriate information sharing among its

[49] Ketchamy, et al, *Group Incentives and Standardization*, Jun 2010
[50] Varanini, ACO Legal Principles, CA Attorney General's Office, Oct 2011

members, may not be legal.[51] Exclusive contracting between a physician and an ACO creates market power because it requires health plans to contract with other participants within the ACO in order to access a specific provider. The exclusive lock-up of a provider that has a dominant market share in a collaboration with other providers has been demonstrated to increase prices without necessarily providing other benefits such as improved quality.[52] Furthermore, exclusive tying of physicians to a hospital may limit the ability of other hospitals to create competing networks.

The issue of physicians in rural areas (and underserved urban areas) is particularly relevant when it comes to exclusivity. The approximately 20% of Californians living in rural areas are served by only approximately 9% of the state physicians, leading to shortages and lack of competition in delivery which can be further exacerbated by exclusivity.[53] Exclusivity can also create challenges for safety-net organizations. For such organizations to meet their mission, they must provide their population with a strong primary care base and access to specialists and hospitals as necessary. Safety-nets are already limited in that some specialists only accept Medicare if they receive a supplemental per-patient Medicare fee. In the frenzy for insurance companies and hospitals to either purchase physician groups or create large coordinated care collaborations, safety-net organizations may be left lacking access to specialists necessary for referral purposes or for their own ACOs. Exclusivity of physicians to an ACO may make it that much harder for ACOs to tap into the specialist network. One way to address this challenge is to provide incentives or rewards for specialists to participate in safety-net ACOs. Another recommendation is that those specialists who require a supplemental Medicare fee be excluded from the number of available specialists calculated in antitrust market share analyses. [54]

To counter some arguments against exclusivity, the practice would allow an ACOs to have a larger patient volume with a given number of providers, thus facilitating the initial financial burden of implementing the ACO. Furthermore, exclusivity can help prevent the "free rider" effect that may come

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[51] ibid

[52] Kamala Harris, *Comments on Proposed Antitrust Policy Statement,* CA Attorney General's Office, May 2011

[53] Freed, *Rural areas try to lure doctors to avert shortage*, CHCF Center for Health Reporting, Jan 2011

[54] Marciarille, *Breaking Down Barriers to Creating Safety-Net ACOs: Federal Statutory and Regulatory Issues*, Aug 2011

from a provider joining multiple ACOs and having little investment in any one ACO's success. Indeed, given the larger number of primary care physicians and their need to manage the general care of a population, exclusivity for Primary Care Physicians may also be more justified than for specialists.[55] However, there may be limits to how much the "free rider" effect can justify the potentially anticompetitive effects of exclusivity, with those limits depending upon such criteria whether the ACO is rural or urban.

In terms of contracting practices between providers and insurers, the Antitrust Policy Statement sets out recommendations on actions for providers to avoid. Some providers, who may have dominance in one area, lock up insurance companies in "all or nothing contracts" whereby the insurance company is required to contract with all providers in a multi-provider network. Blue Shield suggests that ACOs that contract on an "all or nothing" basis should not qualify for the safety zone-harbor provision.[56]

Some providers also currently use their leverage to limit use of cost and quality information by health plans and consumers or to restrict insurers from creating tiered products based on this information. Payers and the California Attorney General's office recommend that providers be required to allow insurers to share quality and cost data with their members. Given a recent California state law (SB 751 passed 9/6/11), hospitals in the state are no longer allowed to bar the disclosure of such information by insurers, but this issue is still relevant for information on physicians and for provider contracts in other states.[57] The Massachusetts Attorney General also recommends prohibitions on contracting practices that prevent insurers from creating limited networks or tiered products.[58] Allowing steering, tiered products, and sharing of quality and cost information can help insurers direct or incentive patients towards higher value providers. Determining whether contracting restrictions are anticompetitive depends upon criteria such as:

- Does the ACO have market power or has it in fact caused anti-competitive effects?

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[55]Page, *Hospital-Physician Relationships & Accountable Care Organizations*, Becker's Hospital Review, Oct 2010
[56]Blue Shield, *Comments Relating to Workshop Regarding Accountable Care Organizations,* Nov 2010
[57] CA Senate Bill 751; Signed into law 09/06/11
[58] Blue Shield, *Comments Relating to Workshop Regarding Accountable Care Organizations,* Nov 2010

- Are those restraints linked to that market power or those anti-competitive effects?
- Is the restraint necessary to the functioning of the ACO itself? If so, is there a less restrictive alternative?
- Is there a procompetitive reason that justifies the restraint or conduct in question against which the market power of the ACO, or the ACO's anticompetitive effects, must be balanced?[59]

Section VI: California Ban on the Corporate Practice of Medicine

The California ban on the Corporate Practice of Medicine, found in the Business and Professions Code Section 2400 of the Medical Practice Act, prevents organizations that are not owned and controlled by healthcare providers from guiding or influencing how care is provided. Care provision includes: outlining appropriate use of diagnostic tests for specific conditions, deciding the need for referrals, determining what treatment options are available to patients, deciding the number of hours worked or number of patients a physician must see. The ban covers management practices as well, including: selection of allied health staff, payer contracting parameters, coding and billing procedures, and selecting medical equipment for the practice.[60] Consideration of the ban and its effects is important because CMS's final rules expressly provide that ACOs must be formed in accordance with state law requirements. Put another way, CMS's final rules do not preclude or preempt application of the ban no matter how much that may discourage formation of ACOs.

There are several downsides to the ban. As independent contractors, physicians are incentivized to invest time and effort into their own practice rather than any one of several hospitals they may utilize. Hospitals have had to utilize monetary incentives to obtain physician cooperation, but this approach depends on striking the right level of reward for very heterogeneous physicians and is challenging to integrate broadly enough to create systematic change. By employing physicians directly, hospitals may be in a stronger position to obtain higher levels of physician commitment, as well as capitalize on

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[59] Varanini, ACO Legal Principles, CA Attorney General's Office, Oct 2011

[60] Medical Board of California, Corporate Practice of Medicine, 2010

screening, socialization, standardization and peer pressure to obtain alignment in care coordination.[61] The current California ban could keep ACOs from hiring physicians or other personnel such as nurses to work with ACO participant physicians in efforts to coordinate care. Additionally, depending on their form, ACO practice guidelines or care coordination requirements might be considered to be directing the provision of care and thus be illegal under the current ban.[62]

However, supporters of the ban argue that hospitals often already have significant power over physicians, particularly those (such as Emergency Room physicians) who cannot practice outside of a hospital. They argue that such control is harmful to the public, as reducing physician autonomy could prioritize hospital profitability above quality care to individuals.[63] Another concern of removing the ban is that strengthening the connection between hospitals and physicians will lead to higher negotiating leverage for both, forcing plans to "take it or leave it" for the combined provider / hospitals entity. Regardless of the current ban, some physician groups do seem to already be quite tied to hospitals, e.g. through the formation of non-profit foundations that employ physicians on behalf of hospitals. This may suggest that, insofar as ACOs may be concerned, the ban may be nothing more than an administrative toll which may need to be paid. Indeed, as one health plan suggested, some hospital systems have already figured out a way to tie physicians to the hospitals and allow them to capitalize on the system's negotiating leverage.[64]

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[61] Cebul, et al, *Organizational Fragmentation and Care Quality in the US,* Journal of Economic Perspectives, 2008
[62]CA Healthcare Foundation, *Accountable Care Organizations in California: Programmatic and Legal Considerations,* Jul 2011
[63] Amici Curiae Brief, *Affiliated Catholic Healthcare Physicians v. Emergency Physicians Medical Group* on behalf of the California Medical Association, et al, Oct 1999
[64] Berenson, et al, *Unchecked Provider Clout in California Foreshadows Challenges to Health Reform*; Apr 2010