May 31, 2011

The Honorable Jon Leibowitz
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

The Honorable Eric H. Holder, Jr.
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530


Dear Chairman Leibowitz and Attorney General Holder:

The Blue Cross and Blue Shield Association (“BCBSA”) appreciates the opportunity to submit comments to the Federal Trade Commission (“FTC”) and the Antitrust Division of the Department of Justice (“Division”) (together, the “Agencies”) on the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (“Proposed Policy”) published in the Federal Register on April 19, 2011.

BCBSA represents the 39 independent Blue Cross and Blue Shield Plans (“Plans”) that currently provide health care coverage to 98 million Americans – roughly 1 in 3. Our Plans offer coverage in every market and every zip code in America. We base the following observations and recommendations on our Plans’ extensive experience pioneering innovative health care payment approaches, including models that are moving away from fee-for-service and toward quality and outcomes-based payment of a nature similar to the proposed design for Accountable Care Organizations (ACOs) operating in the new Medicare Shared Savings Program.
BCBSA supports the overall direction of the Proposed Policy, which we view as generally consistent with the Agencies’ past and current practices in applying the nation’s antitrust laws to the health care sector. We commend the many efforts afoot – both public and private – to improve quality and efficiency in America’s health care system including the establishment of ACOs in Medicare. BCBSA recognizes the importance of clarity concerning not just the Centers for Medicare and Medicaid Services’ (CMS) requirements for the new Medicare Shared Savings Program but also the various legal questions that could be implicated when forming or partnering with an ACO. We applaud the Administration for its effort to release all relevant rulemaking and guidance in coordinated fashion.

Although BCBSA supports the Proposed Policy’s overall direction, we believe the review framework could be strengthened in a number of key respects. Specifically, we recommend that the final version of this enforcement policy:

1. Is explicit that its enforcement framework does not apply to provider collaborations not engaged with Medicare; instead, it should be clear that pre-existing guidance including financial integration requirements continue to apply in such “private market only” cases.

2. Makes clear that a party who contracts with an ACO participating in the Shared Savings Program also qualifies for any protection afforded an ACO under the safety zone or by an Agency’s approval.

3. Requires at least an annual updating of provider service area (“PSA”) market share data and ongoing vigilance, even after Agency approval and while an ACO remains under contract with CMS.

BCBSA believes each of these refinements could be adopted by the Agencies without undermining the basic review structure or broader goals of delivery system reform.

At the same time, BCBSA anticipates the Agencies will receive comments from other stakeholders in support of a less rigorous screening and review policy for ACOs both in and out of Medicare. For example, we have heard discussion in recent weeks of perhaps increasing the maximum PSA share allowed for the antitrust “safety zone” and/or subjecting a smaller subset of entities (only those with PSA market shares approaching perhaps 75 or 80 percent) to mandatory antitrust review. BCBSA urges the Agencies to resist diluting the Proposed Policy in this fashion in light of its consistency with long-standing practice and the fact that the Congress did not legislatively weaken existing antitrust laws for ACOs in enacting the Patient Protection and Affordable Care Act of 2010 (ACA).

A. Collaborations Among Competing Providers Pose Well-Documented Antitrust Risks.

Despite the ACA’s laudable goals in promoting health care delivery system reform through initiatives such as the Shared Savings Program, such goals must not be viewed in a vacuum. The fact remains that competitor collaborations present a significant potential for antitrust risks. On its face, an ACO is a collaboration among otherwise competing entities, which may frequently be proposed in markets already the subject of substantial provider concentration.
Provider collaborations can directly impact the price paid for health care services. While statutory rules govern pricing in the Medicare context, there is nothing to ward off monopolistic pricing or behaviors in the private market should anticompetitive collaborations be allowed to grow with impunity in the name of Medicare reform. Vigorous antitrust scrutiny of ACOs as they continue to evolve is critical.

Antitrust authorities have warned consistently of the harms to competition by collaborations among competing providers. The Agencies have recognized that collective activity among providers can cause anti-competitive increases in the rates paid to them by carriers or other payers whether by directly raising prices or engaging in similar conduct through boycotts. For example, in 1994, Assistant Attorney General Anne Bingaman made the following statements to Congress, underscoring the dangers of provider collaboration:

In health care markets, as in other markets, the antitrust laws have played an integral role in protecting consumers from higher prices resulting from efforts to reduce or eliminate price competition and to thwart cost containment. The antitrust laws have enabled innovative health care delivery systems to form and compete in the market by preventing providers from boycotting those systems.

Five years later, FTC Chairman Robert Pitofsky gave a statement to the House Judiciary Committee underscoring the dangers of provider joint negotiations:

The record of antitrust law enforcement sets forth the impact of collective negotiations” on the public. For example, as described in the Commission’s complaints, collective bargaining by anesthesiologists in Rochester, New York, and by obstetricians in Jacksonville, Florida, forced health plans to raise their reimbursement, and the result was increased premiums for the HMOs’ subscribers. Other cases have challenged actions by associations of pharmacists who succeeded in forcing state and local governments to raise reimbursement levels paid under their employee prescription drug plans. In one such case, an administrative law judge found

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that the collective fee demands of pharmacists cost the State of New York an estimated $7 million.\(^{3}\)

That same year, in a statement before the House Judiciary Committee on H.R. 1304, the Quality Health-Care Coalition Act of 1999, Assistant Attorney General Joel Klein stated:

Our investigations reveal that when health care professionals jointly negotiate with health insurers, without regard to antitrust laws, they typically seek to significantly increase their fees, sometimes by as much as 20-40\%.\(^{4}\)

Just a few years later, the FTC’s Bureau of Competition and Office of Policy Planning warned the Ohio House of Representatives of the possible pernicious effects of unchecked provider collaboration:

Without antitrust enforcement to block price fixing and boycotts designed to increase health plan payments to health care professionals, we can expect prices for health care services to rise substantially. Health plans would have few alternatives to accepting the collective demands of health care providers for higher fees.

The affected parties would likely include consumers, who would be faced with higher insurance premiums and co-payments, as well as their employers. They also likely would include federal, state, and local governments, which would be forced to increase their health care budgets, cut benefits, or reduce the number of beneficiaries covered. Finally the affected parties would likely include the uninsured. Increases in health care costs likely resulting from physician collective bargaining would be expected to increase the number of individuals in this category and strain the resources of both the public and private entities that currently provide for their needs.\(^{5}\)

More recently, antitrust authorities have re-emphasized the importance of competition to health care quality and innovation and the threats that provider collaborations can pose to those important goals. For example, in 2007, the Division’s Litigation I Section Chief, Mark J. Botti, warned the General Assembly of Georgia that government officials should never overlook that market forces


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improve the quality and lower the costs of healthcare services.” Mr. Botti further stated:

During our extensive healthcare hearings in 2003, we obtained substantial evidence about the role of competition in our healthcare delivery system and reached the conclusion that vigorous competition among healthcare providers — promotes the delivery of high-quality, cost-effective healthcare.” Competition results in lower prices and broader access to health care and health insurance, and in particular non-price competition can promote higher quality.

Separate from and in addition to these comments is a long history of enforcement and oversight by the Agencies carefully scrutinizing, and often rejecting, provider collaborations that posed a significant risk to competition (including from higher prices) that outweighed any claimed benefits.

Fortunately, the text of the Agencies’ Proposed Policy reflects a continued recognition that these potential dangers must not be overlooked. As the introduction states:

The Agencies recognize that not all such ACOs are likely to benefit consumers, and under certain conditions ACOs could reduce competition and harm consumers through higher prices or lower quality of care. Thus, the antitrust analysis of ACO applicants to the Shared Savings Program must ensure that ACOs have an opportunity to achieve substantial efficiencies, yet the analysis must remain sufficiently rigorous to protect both Medicare beneficiaries and commercially insured patients from potential anticompetitive harm.”

6 Competition in Healthcare and Certificates of Need (February 23, 2007) (statement of Mark J. Botti, Chief, Litigation I Section, Antitrust Division, United States Department of Justice, before a joint session of the Health and Human Services Committee of the State Senate and the CON Special Committee of the State House of Representatives of the General Assembly of the State of Georgia), available at http://www.justice.gov/atr/public/comments/223754.htm.

7 Id.


The salient point is that the long-settled antitrust landscape on provider collaborations evidences the Agencies’ clear understanding of the genuine anti-competitive harms that unchecked collaborations can inflict. Even though the ACA launched new initiatives such as the Shared Savings Program aimed at efficiency and quality improvement, the plain antitrust risks presented by competitor collaborations remain as real today as they have been at any time. A thoughtful analysis of the Proposed Policy therefore must proceed from a recognition that claims of pro-competitive benefits for arrangements among competing providers should be viewed with a healthy skepticism and require careful scrutiny before they take effect.

B. While the Proposed Policy’s Framework Generally Follows Current Ancillary Restraint Analysis, It Needs Improvement in Several Key Respects.

The Proposed Policy’s analytic framework can provide little antitrust comfort unless the Agencies continue their established practice of carefully ensuring that collaborating providers are truly engaged in pro-competitive activity. The Proposed Policy’s framework thus reflects—again, generally—an endorsement of the accepted analysis for many horizontal arrangements.

At its heart, the Proposed Policy properly confirms that the Agencies will apply a Rule of Reason analysis to most ACOs to determine whether their pro-competitive virtues as set forth in the CMS approval criteria outweigh the competitive harms of permitting providers to negotiate prices together and share competitively sensitive information. Only when a given arrangement is particularly small (under a thirty-percent market share using PSA analysis) would it escape scrutiny altogether and fall into a “safety zone.”

On its face, the Proposed Policy appears to follow the kind of balancing test the Rule of Reason establishes. The Proposed Policy aims to create incentives via the Shared Savings Program for otherwise independent and competitive health care providers to engage in specified types of coordinated conduct that are geared toward providing more cost-effective health care. At the same time, the Proposed Policy correctly recognizes that without appropriate structural and behavioral screens and ongoing compliance requirements, the same policy could result in competitor coordination on price issues and other behavior that could have a severe and diametrically opposite effect on consumer welfare. The ACA does not supply health care providers with antitrust immunity of any kind, or otherwise narrow the Rule of Reason analysis itself. It did not amend the underlying antitrust laws.

The Rule of Reason requires a fact-specific analysis of each case that takes into account a variety of factors, including the history of a restraint, the reason for its adoption, the end it seeks to attain, the structure of the relevant market, and the position in the market of the involved participants.  

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The ultimate goal is to distinguish between practices with anticompetitive effects that are harmful to the consumer and restraints ancillary to other practices that will stimulate competition and benefit consumers with more and better choices at lower prices.  Merely proclaiming that “safety” or patient welfare will be advanced is not enough to satisfy the test. A key focus has to be on the competitive impact of the particular practice. As the Supreme Court made clear in National Society of Engineers, even praiseworthy goals like safety and care are not licenses to flout the antitrust laws. Instead, practices must be carefully scrutinized to consider their effect on competition.

The remainder of this part of our comments sets forth improvements that BCBSA recommends be made before the policy is issued in final form (“Final Policy”).

1. **The Final Policy should make explicit that its enforcement framework does not apply to provider collaborations not engaged with Medicare; instead, it should be clear that pre-existing guidance including financial integration requirements continue to apply in such “private market only” cases.**

The Proposed Policy should be clarified to confirm that it does not supply guidance to provider competitor collaborations that are not engaged in the Medicare Shared Savings Program. For non-Medicare business, the safety zone outlined by the Proposed Policy (and any antitrust approval for ACOs above 30 percent PSA share) differs from the safe harbor under the 1996 Policy Statements because, among other things, the prior guidance required financial integration.

Under the Proposed Policy, there is at least some requirement of financial integration through the savings aspects of the Shared Savings Program -- but that financial integration only goes so far. When it comes to non-Medicare business, there is no requirement of additional financial risk sharing. Under the Proposed Policy, the only requirement is that the same or an essentially similar type of clinical integration exists. This asymmetry raises a concern that other providers may seek to collaborate by adopting the kinds of clinical integration required to be an approved ACO and then citing the Proposed Policy’s factors as persuasive support for Rule of Reason treatment—but without participating in the Shared Savings Program at all.

BCBSA believes the Final Policy should make explicit that any such collaborations would be reviewed under pre-existing guidance and would require financial integration before any protection would be given (as required by the 1996 Policy Statements). The ACO criteria should not be used as an informal guideline of what constitutes clinical integration outside of the Shared Savings Program.

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13 See *Nat. Soc. of Engineers*, 435 U.S. at 696-97 (emphasizing that the Sherman Act protects competition in response to argument that collaborative bidding would promote safety).

14 *1996 Guidelines*, supra, at Section 8 ¶A.4
2. The Final Policy should make clear that a party who contracts with an ACO participating in the Shared Savings Program also qualifies for the protection afforded the ACO under the safety zone or by an Agency’s approval.

The Proposed Policy does not make clear that the parties contracting with an ACO are, in turn, covered by safety zone protection or other approval granted the ACO. Rather, the Proposed Policy only provides protection to providers. Under governing antitrust principles and the common law of conspiracy, however, a party that contracts with an illegal collaboration arguably could be susceptible to claims that it too has engaged in an unlawful agreement. The proposed benefits of the Medicare Shared Savings Program could never take hold if commercial payers (and particularly their provider contracting teams) were legitimately concerned about their own exposure to antitrust claims if they contract with an ACO. Clarifying that a party who contracts with an ACO protected or approved under the Proposed Policy also receives the protection afforded by the safety zone or an Agency’s approval is critical to achieving the broader goals of the Shared Savings Program – to spur widespread delivery system reform.

This concern has real-world bite. Commercial payers have provider contracting staffs who have long and rightfully been counseled by legal departments concerning the degrees to which they can contract with collaborating providers, due specifically to the background law and concerns outlined above. Only by refining the Final Policy to specify that the safety zone and other protections it affords apply equally to other contracting parties (such as a commercial payer) can the Agencies feel confident that its enforcement framework will encourage the very ACO development it seeks to promote.

3. The Final Policy should require at least an annual updating of PSA market share data and ongoing vigilance, even after Agency approval and while an ACO remains under contract with CMS.

The Proposed Policy should require at least an annual updating of PSA market share data until the Agencies and the industry have had more experience implementing the Proposed Policy and reviewing ACO applications. The Proposed Policy does not require any updating of PSA market shares once an ACO has received CMS approval, except if the ACO acquires more providers. BCBSA believes there should be an annual requirement irrespective of whether the ACO has grown by any means (or not at all).

The use of PSAs in antitrust is new. Based on the volume of public comment to date, we expect the Agencies will receive voluminous commentary on the appropriateness of shifting to PSA-based analysis for ACO evaluation. We take no position on the issue and neither endorse nor reject the use of PSAs (though we recognize that the Agencies are seeking an expedient proxy for market share). Regardless of how the Agencies address PSA commentary, however, the reality is that the Agencies are breaking new ground in using PSA data for these purposes.

Undoubtedly there will be lessons learned as the Agencies and the industry become more adept with the use of PSAs. Until a greater breadth of experience is developed, the Final Policy should require regular updating of actual PSA shares of approved ACOs to help determine their ongoing

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15 Proposed ACO Statement, supra, at 21898 n. 36.
market impact. This updating should be effectuated by ongoing submission to the Agencies of PSA data by the ACO, on at least an annual basis (or more frequently if data becomes more readily available).

To be sure, this proposal will impose some additional reporting requirements. We believe the marginal burden of regular updating is substantially outweighed by a critical need to ensure that lessons learned in early stages of implementation of the Proposed Policy are applied to review of new or even existing ACOs. If an ACO exceeds the market share thresholds at any point during its approval period, it should no longer receive safety zone protection or an exemption from mandated review.

C. Vigorous Application of the Proposed ACO Statement’s Principles Is Critically Important.

Notwithstanding the observations and suggested improvements detailed above, it is certain that vigorous antitrust oversight and enforcement by the Agencies will be the single most effective protection for competition in the health care marketplace as ACOs develop and take hold. Since at least 1993, the Agencies have actively monitored and analyzed new developments in the health care field.¹⁶ While the Medicare Shared Savings Program would seem to hold great promise for achieving efficiencies and health care quality improvements, the model’s inherent reliance on collaborations among competitors raises the potential for dangerous anticompetitive effects in the broader health care marketplace. Whether the potential for good or for harm becomes the greater reality cannot be fully known at this time.

Unlike the more familiar scenarios presented by financial integration among otherwise competing providers, clinical integration lacks any direct financial incentive (outside of shared savings) to achieve efficiencies.¹⁷ Clinical integration aims to achieve efficiencies through organized, cooperative activity among providers.¹⁸ By its nature, then, this type of integration requires an initial period of carefully scrutinized real-world experience before the Agencies or anyone in the marketplace can comfortably conclude that such activity is truly pro-competitive. Unmonitored, the proposed integration among competing providers might either be ineffective in practice or prove to be –simply a pretext to avoid per se condemnation.”¹⁹

¹⁶ 1996 Guidelines, supra, at Introduction.


Whether ACOs will achieve the sorts of transformational efficiencies envisioned by the ACA therefore will depend on the Agencies’ continued involvement. The Agencies have expressed varying degrees of caution concerning the impact of clinical integration, emphasizing that it is a fairly recent development.\(^{20}\) Agency pronouncements and advisory opinions have raised concerns over the lack of empirical data.\(^{21}\) Even where integrated arrangements have been approved, the Agencies have implemented protocols for continued review and emphasized the need for constant vigilance.\(^{22}\)

Following that trend, we urge the Agencies to scrutinize carefully the supporting information submitted by proposed ACOs to determine whether they truly do satisfy the Rule of Reason test. We further urge the Agencies to monitor closely the actual competitive effects of ACOs as the Shared Savings Program is fully implemented and ACOs continue to evolve in the marketplace.

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BCBSA appreciates the Agencies’ consideration of our comments and recommendations for refining the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program. If you have any questions, please contact Lisa Joldersma at (202) 626-4785 or lisa.joldersma@bcbsa.com.

Sincerely,

Justine Handelman
Vice President
Legislative and Regulatory Policy
Blue Cross Blue Shield Association

\(^{20}\) See Rosch, Leary, \textit{supra}.

\(^{21}\) See \textit{Clinical Integration: The Changing Policy Climate and What It Means for Care Coordination} (April 27, 2009) (remarks of Pamela Jones Harbour, Commissioner, before the American Hospital Association Annual Membership Meeting), \textit{available at} \url{http://www.ftc.gov/speeches/harbour/090427ahaclinicalintegration.pdf} (―A s we heard during the Commission’s clinical integration workshop last May, there have been very few empirical studies of clinical integration outcomes‖).

\(^{22}\) Letter from Jeffrey W. Brennan, Assistant Director Health Care Services & Products, Federal Trade Commission, to John J. Miles, Ober, Kaler, Grimes & Shriver (February 19, 2002), \textit{available at} \url{http://www.ftc.gov/bc/adops/medsouth.shtm}; Letter from Markus H. Meier, Assistant Director, Federal Trade Commission, to Christi J. Braun and John J. Miles, Ober, Kaler, Grimes & Shriver (September 17, 2007), \textit{available at} \url{http://www.ftc.gov/bc/adops/gripa.pdf}; Letter from Markus H. Meier, Assistant Director, FTC, to Christi J. Braun, Ober, Kaler, Grimes & Shriver (April 13, 2009), \textit{available at} \url{http://www.ftc.gov/os/closings/staff/090413tristateaoletter.pdf}. A similar emphasis on empirical results can also be found in the subsequent \textit{Greater Rochester} and \textit{Tri-State} decisions.