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The Honorable Christine A. Varney
Assistant Attorney General,
Antitrust Division
United States Department of Justice
950 Pennsylvania Ave., NW
Washington, D.C. 20530

The Honorable Jon Leibowitz
Chairman
Federal Trade Commission
6th Street and Pennsylvania Ave., NW
Washington, D.C. 20580

Re: Comments on Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program

Dear Ms. Varney and Chairman Leibowitz:

The American Benefits Council (the "Council") appreciates the opportunity to provide comments to the Federal Trade Commission ("FTC") and the Antitrust Division of the Department of Justice ("DOJ") (together, "the Antitrust Agencies") on the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program. 76 *Fed. Reg.* 21,894 (April 19, 2011) ("the Proposed Statement").

The Council is a public policy organization representing principally Fortune 500 companies and other organizations that assist employers of all sizes in providing benefits to employees. Collectively, the Council's members either sponsor directly, or provide services to, retirement and health plans that cover more than 100 million Americans.

The Council applauds the work of the Antitrust Agencies reflected in the Proposed Statement and their cooperation with the Centers for Medicare & Medicaid Services ("CMS") in helping ensure that competition and antitrust-related concerns are appropriately brought to bear for accountable care organization ("ACO") initiatives.

In this letter, we identify some key points on which we strongly support the approach taken by the Antitrust Agencies. We also identify a few discrete points on which we recommend that the Agencies provide additional guidance or modify thresholds contained in the Proposed Statement.

A. Mandatory review for ACOs exceeding a specified Primary Service Area share threshold

The Council supports CMS's requiring competition-focused review of ACOs applying to participate in the Medicare Shared Savings Program ("SSP") whose participants have a share exceeding a specified threshold in any common service line served by any two or more of the ACO participants. We also support the approach proposed by the Antitrust Agencies to effectuate that review. This proposed review process signifies a valuable recognition by CMS of the important role of competition in protecting the interests of individuals as patients and Medicare beneficiaries, protecting the Medicare program and protecting the health care services marketplace generally, in which the Medicare program and its beneficiaries, as well as employers and consumers all participate.

The harms that can result from increases in, and exercises of, market power in the delivery of health services are severe. Even a modest increase in the cost of health care services at a local level can result in many millions of dollars of additional cost to the Council's members and to the employees, retirees and family members they cover. Similarly, an anticompetitive ACO that blockades creation of other ACOs or Medicare health care delivery programs, such as Medicare Advantage plans, could undermine the intended goals of the Medicare SSP and harm private payors as well.

Advance antitrust screening in this instance is a sound measure, particularly where the government is offering the prospect of additional funding to organizations that form via partial integration of competitors. In short, the government will itself be incentivizing and stimulating changes in the patterns and organization of health care delivery, consciously seeking to spark combinations and integrations of otherwise independently competing health care providers to achieve the laudable objectives of the Medicare SSP. The government has recognized that this effort must be tempered by concerns that serious harms are likely to result if the changes are exploited by providers to create bottlenecks or obstacles to competition.

The prospect of antitrust law enforcement cannot be counted upon to deter or catch and prevent before harm occurs every inappropriate accretion of market power. Moreover, once "broken," it is very hard to "fix" competition in health care markets after competition has lost dynamism and market power is entrenched. After-the-fact antitrust enforcement can take years and may be inadequate to prevent harm to consumers and restore competition. Breaking up arrangements that are nothing more than cartels or price-fixing conspiracies would not face the same "unscrambling the eggs" difficulties, but

in cases where providers are achieving, or at least purporting to achieve, significant clinical integration and operational efficiencies through ACO arrangements, after-the-fact break-up remedies could in some instances be very difficult. This also means that advance screening can prove valuable to providers. By signaling that a possible ACO is unlikely to trigger a challenge on antitrust grounds, screening reduces the risk provider organizations might otherwise perceive when investing time and resources into ACO planning and operations.

Moreover, while there are glitches to be worked out, we applaud CMS and the Antitrust Agencies for specifying an initial screening mechanism that avoids subjectivity and a need for "reasonableness" judgments. As we understand the Proposed Statement, the Primary Service Area ("PSA") based mechanics are to be used to determine what level of inquiry or review is required, and are not to be understood as altering the substantive guidance on provider network formation and operation that have long been articulated by the Antitrust Agencies and the courts. We recommend that the Antitrust Agencies make this more explicit in the Proposed Statement.

B. Adjusting PSA share thresholds for "safety zone" and mandatory review

The Proposed Statement sets out criteria for a new antitrust "safety zone" for ACOs participating, or seeking to participate, in the Medicare SSP. Using a new PSA screening tool, page 7 of the Proposed Statement provides that: "For an ACO to fall with the safety zone, independent PSA participants (e.g., physician group practices) that provide the same service (a "common service") must have a combined share of 30 percent or less of each common service in each participant's PSA, wherever two or more ACO participants provide that service to patients from that PSA."

In addition, under CMS's proposed rule and the Proposed Statement, ACOs with a combined PSA share in any common service of more than 50 percent would be required to provide CMS with a letter from one of the Antitrust Agencies stating that the reviewing Antitrust Agency has no present intention to challenge or recommend challenging the ACO under the antitrust laws.

Use of a PSA measure and accompanying share thresholds in formal Antitrust Agency guidance is new and a departure from the "market" based thresholds used for "safety zone" guidance in the 1996 *Statements of Antitrust Enforcement Policy in Health Care*. Statement 8 from the 1996 guidance, for example, establishes safety zones for "exclusive" and "non-exclusive" physician network joint ventures whose physician participants share financial risk and are 20 percent or less, or 30 percent or less, respectively, of each physician specialty with active hospital staff privileges who practice in the "relevant geographic market". Antitrust analysis on the merits in court and administrative proceedings also typically depends on determination of a relevant product and geographic market.

The Council appreciates that the Proposed Statement, in its reliance on the PSA measure as a screening tool, seeks to provide clarity, transparency and relatively greater confidence for providers considering participation in an ACO. Thus, clearly defined instructions for determining PSAs and calculating PSA shares will let ACOs identify when they are in a safety zone and when a mandatory review is required, without having to undertake a substantive market analysis.

We understand that the Antitrust Agencies do not consider the new PSA-based screening tool to itself be a basis for identification or determination of the proper metes and bounds of a relevant geographic or product market for antitrust analysis. Nor are the PSA share thresholds that have been proposed intended to be a determinant of the presence or absence of market power. Rather, we understand that the PSA safety zone share caps and the mandatory review threshold are tools to help identify situations exceedingly unlikely to raise antitrust concerns, as to the former, and warranting more careful review, as to the latter.

However, because the PSA share screen is not an actual measure for determining relevant product and geographic markets and the market share in such markets, it is essential that the screen not be over-inclusive for the safety zone, or under-inclusive in flagging those ACOs that require close review. The harms to competition from anticompetitive behavior in health care services markets can be severe. The Antitrust Agencies should be loathe to use an untested screening measure and accompanying share threshold to create a "safety zone" if the results would be to permit anticompetitive ACOs to qualify for safety zone status. This concern cannot be discounted given uncertainty about the correlation between PSA designation and actual geographic market shape and size.

The existing safety zone under Statement 8 of the 1996 guidance provides protection for qualifying physician network joint ventures with a 20 percent market share or less where physicians in a specialty are exclusive, and 30 percent market share or less where physicians are not exclusive. It is not clear how often the PSA tool will produce an area that is materially larger or smaller than actual geographic markets. Moreover, the Proposed Statement would expressly permit safety zone status, regardless of participating provider exclusivity for non-hospital and non-ASC providers, where the PSA share is 30 percent or less in common areas of service for ACO participants, in contrast to the 20 percent threshold in Statement 8 of the 1996 Statement.

The Council is concerned, apart from the untested nature of the PSA screening measure, about the switch to a 30 percent threshold where exclusivity is present. In other words, assuming that the PSA tool were an accurate predictor of the contours of the applicable geographic market, a 30 percent safety zone for joint ventures of competitors that entail exclusivity would effectively assign automatic approval, absent extraordinary circumstances, to contracting that would create a market structure with only three provider network organizations and, via exclusivity, three pathways for private plan provider contracting throughout the marketplace. This would be the result if three such

ACOs were established, leaving only 10 percent of the market's providers independently available to participate either directly or via any other ACO with private health plans -- a panel breadth that is typically insufficient for viability, including for marketplaces in which the Council's member employers purchase services. In the absence of reliable grounds for believing that PSA shares will consistently overstate actual market shares, the Council is seriously concerned about this step and opposes it. A safety zone, by definition, should be designed with caution. While it is a given that some lawful activities will be outside the safety zone, the safety zone itself should not be accessible for anticompetitive arrangements.

The Council recommends therefore that the safety zone screen in the Proposed Statement should be changed from 30 percent to 20 percent where two or more providers in the ACO provide a common service. Or, in the alternative, the safety zone should be set at 20 percent for any common service line where there is exclusivity for the affected ACO participants. If, over time, experience teaches that a change to a 25 or 30 percent threshold could be safely made, an adjustment could then be made. For now, though, we note that, as CMS recognized in its recent announcements with regard to "Pioneer" ACOs, there are many provider sponsored ACO-type ventures that have already been formed and that have been operating, in some cases for many years. Even more of these organizations have been formed recently. This activity has blossomed without need for any substantive relaxation of the guidance contained in the 1996 enforcement policy statement.

Similarly, the CMS proposed regulation and the Proposed Statement set a 50 percent threshold for the mandatory antitrust review requirement. The Council is concerned that this threshold is too high. In health markets, an ACO with between 40 and 50 percent of the primary care physicians could very likely have the potential to exercise market power. Again, given uncertainty about the predictive value of PSAs as proxies for geographic market definition in an antitrust screening tool, and, moreover, the potential that ACO entities may have exclusivity arrangements with 50 percent of the primary care physicians or even specialists for commercial health plan products without triggering mandatory review under the Proposed Statement, the Council believes that the proposed 50 percent threshold is too high. While we recognize that just because an entity is not required to obtain a prior antitrust view does not mean it will have antitrust protection, we believe nonetheless, that the mandatory review threshold, given the way exclusivity for physicians is addressed in the Proposed Statement, should be lowered. We suggest 40 percent as a reasonable breakpoint, and believe this step is especially important where exclusivity is involved. This level could be revisited in the future once there is a track record on the predictive value of the PSA tool and some experience with Medicare ACOs operating in the commercial marketplace.

C. Guidance to ACOs below or above mandatory review threshold on means to potentially reduce antitrust risk

The Proposed Statement outlines fives types of conduct that an ACO below the mandatory review threshold can avoid to reduce significantly the likelihood of an antitrust investigation. Generally, these include (1) preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers through "anti-steering," "guaranteed inclusion," "product participation," "price parity" or other similar clauses; (2) expressly or implicitly tying purchase by commercial plans of the ACO's services to purchase of other services from affiliates ACO providers, or vice versa; (3) contracting with physician specialists, hospitals, ASC's and other non-primary care physician providers on an exclusive basis, so as to prevent or discourage them from contracting outside the ACO either individually to through other ACOs or provider networks; (4) restricting a commercial payer's ability to make cost, quality, efficiency and performance measure data available to enrollees; and (5) sharing among ACO participants competitively sensitive price or other data that could be used to set prices or other terms of dealing for services outside the scope of the ACO.

While the presence of any of these behaviors does not, of course, show that there has been an antitrust violation, we support the Antitrust Agencies' highlighting these types of conduct as potential risk factors. Notably, though, item (3) does not address exclusive contracting with primary care physicians. It is true that within the Medicare SSP initiative, primary care physicians must be exclusive with a single ACO. It is not at all the case, however, that primary care physicians must be exclusive to a single physician network in the commercial plan arena. Primary care physicians may contract with multiple health plans, as well as with one or more physician or provider network organizations. The vehicle through which the ultimate health plan purchaser contracts to access that physician's services will dictate the contractual terms and the network configuration that will apply. Certainly, some primary care physicians may elect to contract with a single ACO, and some ACOs may appropriately employ exclusivity arrangements with primary care physicians where doing so does not unreasonably obstruct competition. Such exclusivity may in some instances foster greater efficiency and improved patient care. Even so, though, risk mitigation factor (3) is inappropriately silent about exclusive contracting with primary care physicians. This is particularly so given the Proposed Statement's comment that ACOs avoiding the five listed types of conduct are "highly unlikely to present anticompetitive concerns." Thus, the Proposed Statement should be modified to highlight that exclusive contracts with primary care physicians in the commercial plan context can be a risk factor as well, if a substantial portion of the available physicians are so committed. Finally, we concur with the Antitrust Agencies' confirmation that exclusivity for purposes of the Proposed Statement's construction should be evaluated on the basis of actual provider behavior, and not solely on the basis of contractual requirements.

D. Cost shifting, market power and private payer plan cost considerations

Private health plan purchasers typically pay more for the same health services than government payers such as Medicare and Medicaid.[1] There is a long history of concern that reductions in payment under government health programs can result in "cost-shifting" to commercial health plan purchasers.[2] A crux of such concern is that reductions in government payments may, in effect, cause increases in the costs actually incurred by commercial plans. Scholars have taken issue with the "cost shifting" characterization, arguing that providers' ability and incentive to raise prices or increase costs to private payers is in fact principally a function of market power and local market conditions and that there is no or only a limited connection between rates of payment under government programs and costs imposed on private health plans.[3] It is not necessary for the Antitrust Agencies to resolve or even address the long-standing controversy on the impact on private sector payers of reductions in payment under government programs to recognize the importance of the latter concern, which is salient here and subject to no reasonable dispute – i.e. that the ability of providers to impose higher costs and prices on private plans is in key respects a market power question.

In the Medicare ACO context, the Antitrust Agencies are dealing with a federal government sponsored attempt to induce reforms in the way health care services are provided to Medicare beneficiaries. These reforms involve new collaborations and combinations among otherwise competing health care providers. The government has recognized that for the reform to take hold it may well need to find root in the private health plan marketplace as well. It is essential, therefore, that the Antitrust Agencies take great care to avoid a particular kind of "cost shift" or cost impact – i.e., imposition of higher costs on private plan payers resulting from anticompetitive consolidations, combinations, and collaborations undertaken in purported response to the government's invitation for ACO Medicare SSP participation.

Numerous scholars and studies have recognized that concentrated market power in the delivery of health care services is a cause of higher prices and costs and also that ACOs pose exactly that risk, if antitrust safeguards are not effective.[4] The Medicare Payment

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[1] See, e.g., Reinhardt, U., The Pricing of Hospital Services: Chaos behind a Veil of Secrecy, *Health Affairs* 25 (1) (2006) at pp. 57-69; Ginsburg, P., Can Hospitals and Physicians Shift the Effects of Cuts in Medicare Reimbursement to Private Payers? *Health Affairs*, October 2003.

[2] See, e.g., Morrisey, M., Hospital Cost Shifting, A Continuing Debate, *EBRI Issue Brief* (December 1996 (180);

[3] Frakt, A., How Much Do Hospitals Cost Shift? A Review of the Evidence, *The Milbank Quarterly*, Vol. 89, No. 1, 2011 (p. 123) (suggesting that some cost shifting as a result of reductions in payment by government programs is possible, but likely at a rate close to twenty cents on the dollar)

[4] See, e.g., Vogt, W.., and R., How Has Hospital Consolidation Affected the Price and Quality of Hospital Care, *RWJF Research Synthesis Report* 9 (Feb. 2006) Capps, C., D. Dranove, and M. Satterthwaite, Competition and Market Power in Option Demand Markets, *RAND Journal of Economics* (2003) 34 (4): 737-63); Wu, V., Hospital Cost Shifting Revisited: New Evidence from the Balanced Budget Act of 1997. *International Journal of Health Care Finance and Economics*, published online, August 12, 2009.

Advisory Commission has warned that "One danger [of ACOs] is that physician groups consolidate into larger entities and use this negotiating power to increase prices charged to private insurers."[5] Another group of experts has warned:

> If [ACOs] lead to more integrated provider groups that are able to exert market power in negotiations – both by encouraging providers to join organizations and by expanding the proportion of patients for whom provider groups can negotiate rates – private insurers could wind up paying more, even if care is delivered more efficiently.[6]

The March 2010 report by Massachusetts Attorney General Martha Coakley[7] made a key finding that price increases in provider services caused most of the increase in health care costs during the past few years in Massachusetts. The report suggests that market consolidations and combinations have contributed to this rise in prices and cost, and that increased prices are not explained by efficiencies or improvements in quality or health outcomes.[8]

The benefits of competition and of strict but fair antitrust enforcement should not be sacrificed as regards any entities participating in the Medicare SSP program.

It is a key responsibility of the Antitrust Agencies, therefore, to assure that private parties' activities in response to the Medicare SSP initiative stay wholly within the bounds of the antitrust laws and do not create or entrench market power, both as regards impact on Medicare beneficiaries and the Medicare program, but also, and critically, as regards impact on the private plan marketplace. To protect against the latter risk, we recommend

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[5] Medicare Payment Advisory Commission, Report to Congress, "Improving Incentives in the Medicare Program" (June 2009) at pp. 55-56.

[6] Berenson, Ginsburg, & Kemper, "Unchecked provider clout in California foreshadows challenges to health reform," *Health Affairs* 699-705 (April 2010):

[7] Massachusetts Health Care Cost Trends Final Report, Appendix B: Report Issued by the Office of the Attorney General Martha Coakley, March 2010. Other findings were that price variations in payments by health insurers to providers are correlated to market leverage as measured by the relative market position of the hospital or provider group compared with other hospitals or provider groups within a geographic region or within a group of academic medical centers and that higher priced hospitals are gaining market share at the expense of lower priced hospitals, which are losing volume. Large health care providers have a great deal of leverage in negotiations because insurers must maintain stable, broad provider networks, the report suggests.

[8] A report commissioned by the American Hospital Association, in contrast, is critical of reports that provider organization size and provider consolidation are primary drivers of price increases. See M. Guerin-Calvert and G. Isreilevich, "A Critique of Recent Publications Claiming Provider Market Power," at p. 38 (October 2010). Ultimately, one need not accept the specific findings or methods of any particular study to recognize that consolidation of power in the delivery of health care services must be an important and critical antitrust concern. The AHA-commissioned report, for example, acknowledges that evaluations in this arena "should be based on sound economic principles and an examination of very specific facts and circumstances."

that applying ACOs, at least those outside the safety zone, be required to submit with their initial application, and in annual updates, their negotiated rates of payment with commercial payors and that this information be shared with the Antitrust Agencies. This will help CMS monitor for increased differentials between Medicare and commercial payment rates, which could be a signal that there may be difficulty in sustaining ACO providers active commitment to providing access to existing and new Medicare patients. This information would also be valuable to the Antitrust Agencies in identifying and guarding against anticompetitive price increases to private plan payers.

E. Organizations formed prior to March 23, 2010

The Proposed Statement applies only to ACO entities formed after March 23, 2010. CMS is anticipating working with some already operational ACO entities through its "Pioneer ACO" initiative. It appears therefore that already existing provider network or delivery organizations could, if they wished, participate in the basic ACO program or in the Pioneer initiative. They might, under the basic program, do so under an "advanced" incentive arrangement program that CMS has announced it is considering. While already existing entities may not need the comfort of the safety zone to give them confidence to enter the marketplace, the Council does not believe there is a legitimate reason to excuse existing entities from the mandatory antitrust review screening process, whether they are seeking to participate in the basic or the Pioneer program.

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Thank you for this opportunity to provide comments. We would be available to answer any questions the staff of either Antitrust Agency may have.

Sincerely,

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Kathryn Wilber
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