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May 31, 2011

Federal Trade Commission
Office of the Secretary
Room H-113 (Annex W)
600 Pennsylvania Avenue, NW
Washington, DC 20580

United States Department of Justice
Antitrust Division
Office of the Assistant Attorney General
950 Pennsylvania Avenue, NW
Washington, DC 20530

RE: Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating In the Medicare Shared Savings Program, Matter V1000017

Submitted via https:///ftcpublic.commentworks.com/ftc/acoenforcementpolicy.

Dear Sir or Madam:

We are writing on behalf of America's Health Insurance Plans (AHIP) in response to the Request for Comments by the Federal Trade Commission and the Department of Justice (the "Agencies") with respect to their *Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* ("Policy Statement"). The Policy Statement reflects the Agencies' proposed enforcement policy with respect to entities that seek to participate, or have otherwise been approved to participate, as accountable care organizations (ACOs) under the Medicare Shared Savings Program ("Shared Savings Program" or "Program"), Section 3022 of the Patient Protection and Affordable Care Act (PPACA), which was signed into law on March 23, 2010.[1]

[1] Pub. L. No. 111-148, as amended by Pub. L. No. 111-152.

AHIP is the national association representing approximately 1,300 health insurance plans that provide coverage to more than 200 million Americans. Our members offer a broad range of health insurance products in the commercial marketplace and have demonstrated a strong commitment to participation in public programs. AHIP's members also have been leaders in collaborations and other efforts to transform the health care system to one that rewards value instead of volume, improves quality and efficiency, and uses information as a tool, rather than a barrier, to better care.

We appreciate the opportunity to comment on the Policy Statement. The Agencies, the Department of Health and Human Services (HHS), and its Centers for Medicare and Medicaid Services (CMS) recognize that successful efforts to move the health care delivery system to one that delivers higher quality, more efficient care, must rely upon, rather than displace, the key principles of competition policy as articulated and enforced by the Agencies. Attempting to improve the care provided to Medicare beneficiaries by allowing providers to acquire, enhance, or inappropriately exercise market power will not only lead to higher prices and lower quality in commercial markets, but will undermine the very goals that CMS is pursuing for Medicare beneficiaries. Therefore, we appreciate that the agencies are pursuing two vital aspects of positive delivery system change: (1) seeking to ultimately move from entities that deliver care in a fragmented fashion to entities that deliver more coordinated care; and (2) preserving an environment in which those entities compete, to the benefit of consumers, to deliver the highest quality and most efficient care.

The Agencies have set forth a framework that, we believe, attempts to balance the goals of providing sufficient guidance and an efficient process to entities seeking to participate in the program ("Program Applicants"), while ensuring that there is sufficient review of such entities that could potentially harm consumers from the aggregation or inappropriate exercise of market power. The Policy Statement pursues this balance through a screening mechanism that helps the Agencies determine the level of review appropriate for various categories of Program Applicants. We do not understand the Agencies to propose, and we certainly do not advocate, any change to the substantive law and principles that guide substantive antitrust analysis of Program Participants and other entities.

We do believe that some *modification* of the balance set forth by the Agencies is advisable in light of two key considerations:

- First, the Shared Savings Program and everything that accompanies it, including the review process in the Policy Statement, is new. This suggests that the Agencies should make choices that lead to more, rather than less, review, while the Shared Savings Program, the Policy Statement, and the entities participating in the Shared Savings Program ("Program Participants") are tested by implementation.

- Second, as explained in more detail below, the potentially significant cost to consumers of not reviewing Program Participants that could exercise market power dwarfs the modest cost of reviewing additional Program Participants that would be subject to review.

Following these guiding considerations, in the third section of this letter we have specific recommendations for revisions to the Policy Statement. As a preliminary matter, however, we think it useful to discuss: (1) two developments in commercial healthcare markets that form important context for the Policy Statement and (2) what the Policy Statement should be designed to achieve in light of that context and the goals of the Shared Savings Program.

I. *The Policy Statement Should be Viewed in the Context of Two Important Developments in Commercial Healthcare Markets*

As recognized by the Agencies and others, the Shared Savings Program will not occur in a vacuum. Rather, the Program will impact, and be impacted by, commercial health care markets. Thus, as a preliminary matter, it is important to understand two developments in those markets that are likely to impact, and may be impacted by, the Shared Savings Program. First, provider markets have become very concentrated, largely through consolidation, and this trend is expected to continue. Second, prior to the Program, and in the absence of any antitrust "relief," private plans and providers have established a wide range of ACOs and other innovative structures to provide patients with more coordinated, higher quality, and more efficient care. In combination, these factors suggest that ACOs can deliver coordination and improvements in quality and efficiency without sacrificing antitrust goals.

A. *The Policy Statement Should be Viewed Against a Backdrop of Concentrated Provider Markets that Have Led to Higher Prices and Other Consumer Harms*

An analysis of the antitrust treatment of the Shared Savings Program, which contemplates changes to the health care delivery system, should begin with an understanding of the current state of competition in that system. Among those who have examined this issue, there is general consensus that provider markets have become more concentrated over time and that hospital markets, in particular, are highly concentrated. In fact, a recent analysis performed by Cory Capps, PhD, of Bates White and Professor David Dranove of Northwestern University, on behalf of AHIP, concluded that hospital ownership is "highly concentrated" in just over 80% of metropolitan statistical areas (MSAs).

This reflects a trend that dates back to the 1990s of hospital capacity shifting from independent hospitals towards multi-hospital systems. By 2009, the average of MSA-level concentration, as measured by the Herfindahl-Hirshman Index (HHI), had reached roughly 4,700, over 2,000 above the Agencies' threshold for a "highly concentrated" market. This context is important because the Program may lead to an increase in provider market concentration through consolidation, and those who have examined previous provider consolidation concluded that it harmed consumers through higher prices and lower incentives to improve quality.

Thus, consumers have reason to worry if the Program will lead to a further consolidation similar to the wave of hospital consolidation in the 1990s that "raised prices by at least five percent and likely by significantly more."[2] The continuing cost to consumers of provider market power was demonstrated by a 2010 a Massachusetts' government study on Health Care Cost Trends. The Study concluded that provider price increases were the most important factor driving rising health care spending and that price variations among hospitals were not correlated to the quality of care.[3]

Of course, not all consolidation is anticompetitive. The existence of highly consolidated provider markets, however, suggests reason for caution with respect to the consolidation likely to follow from the Shared Savings Program. It is important that, as the Program attempts to

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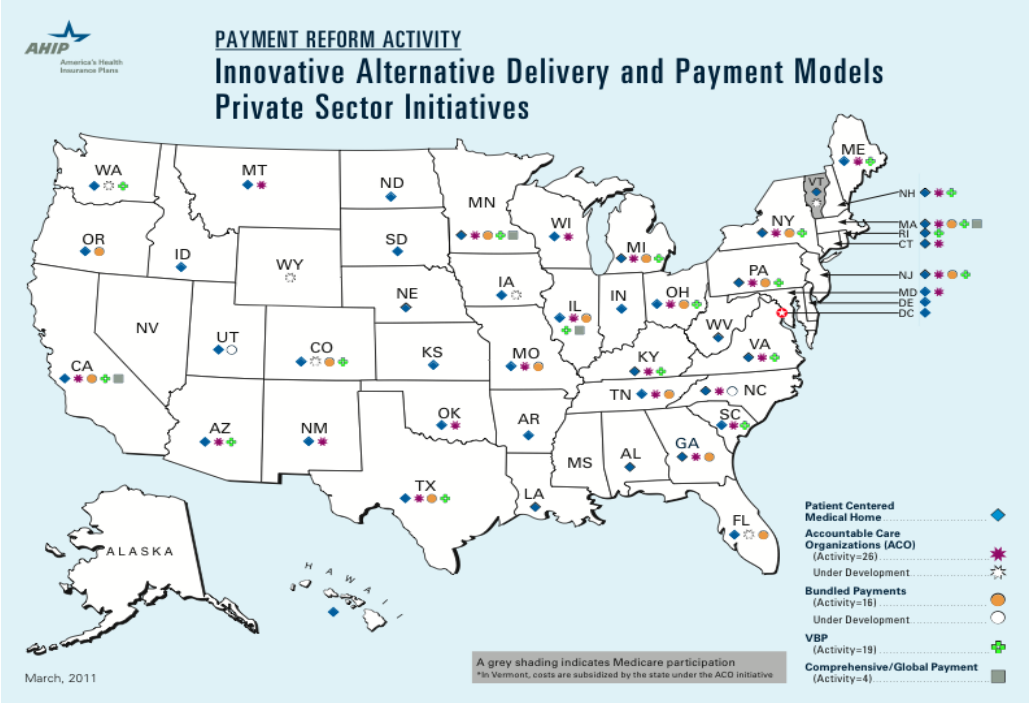
[2] Vogt, W. and R. Town. *How Has Hospital Consolidation Affected the Price and Quality of Hospital Care?,* RWJF RESEARCH SYNTHESIS REPORT No. 9, Feb. 2006.

[3] Massachusetts Health Care Cost Trends, 2010 Final Report, *available at:* http://www.mass.gov/Eeohhs2/docs/dhcfp/cost_trend_docs/final_report_docs/health_care_cost_trends_2010_final_report.pdf.

encourage collaborations among providers that will benefit consumers, it not allow collaborations that will harm them through market power. The antitrust laws and Agency practice provide a well-tested approach for distinguishing collaborations that are pro-competitive from those that are not. While the Shared Savings Program contains a number of evaluative measures, the most critical measure generated by the Program will be an outcome measure: whether the Program will lead to higher prices and other consumer harm by leading to even more provider entities with market power (or to provider entities with even more market power), or whether it will lead to higher quality more efficient care, by encouraging provider collaborations that are not based on the aggregation of market power.

B. *Private Health Insurance Plans and Providers Have Created ACOs and Other Innovative Structures that Benefitted Consumers Without any Need for "Relief" from the Antitrust Laws*

Over the past several years, health insurers have partnered with providers – hospitals and physician groups – to promote accountable care models that are transforming the delivery system by offering better care at lower cost. These partnerships offer multiple dimensions of health plan support – the provision of tools and data to support population based care, programs and staff to better coordinate care, and the redesign of provider contracts to reward the achievement of high quality performance and cost reduction goals. The number of accountable care models continue to evolve at a rapid pace, as health insurers renegotiate provider contracts to focus on population-based care and better address gaps in care and reward quality and efficiency through shared savings, shared risk, and other payment models. The attached map illustrates a snapshot of such activity currently under way and growing rapidly.



These partnerships have been developed under existing antitrust guidance and are benefiting consumers with better care while constraining health care cost. The Shared Savings Program should reinforce these efforts, not undermine them. Consumers will be well served by robust and varied initiatives to design the best approaches to improving quality and efficiency, including efforts involving partnerships between plans and providers. They will be best served if these collaborations and other efforts compete vigorously against a range of other approaches, entities, and collaborations to create the most innovative, effective, and accountable approaches. If the Program leads to provider market power that reduces provider incentives to participate in these activities, or otherwise undermines such activities, it will have failed another key *outcome* measure of the Program's success.

II. *The Policy Statement Reflects a Rare, and Important, Opportunity to Systematically Address Important Competition Concerns*

Before discussing the Policy Statement itself, it also is important to discuss several aspects of the Shared Savings Program. The Shared Savings Program is a program for Medicare beneficiaries, but it will have a significant impact on commercially-insured patients as well. Thus, the Agencies noted recent commentary suggesting that "health care providers are more likely to integrate their care delivery for Medicare beneficiaries through ACOs if they can also use the

ACOs for commercially insured patients."[4] Entities formed for the Shared Savings Program are unlikely to deconstruct themselves for commercially-insured patients and, if such entities possess market power, they are likely to exercise it by charging higher prices to, and engaging in other activities to the detriment of, such patients.

The Shared Savings Program is both ambitious and modest in its goals. It is ambitious in the sense that it is part of a larger effort to transition the delivery system to one focused on coordinated care that improves both quality and efficiency. It is modest both in its limited scope (i.e., only to a subset of Medicare beneficiaries) and in its limited tools (i.e., it builds upon, rather than replaces, fee-for-service payment model).[5] While a series of modest steps may well be the best means of reaching an ambitious goal, policymakers must always remain vigilant that the steps are likely to achieve the goal.

In this context, the Shared Savings Program will not be a step towards an improved delivery system that provides better and more efficient care if it leads to modified fee-for-service care delivered by providers with newly acquired or enhanced market power. Such a result would harm both those with commercial insurance and Medicare beneficiaries. The most obvious harm would be higher prices for the commercially-insured, as providers exercised their market power through charging higher rates. Commercial patients would suffer a range of other potential harms, as market power would diminish incentives for various forms of non-price competition, from participation in innovative arrangements, to the sharing of cost and quality information, to engaging in efforts to improve the quality of care. While the nature of Medicare reimbursement means that its beneficiaries would not be impacted by the higher prices, at least directly, Medicare beneficiaries would suffer from reduced incentives for providers to engage in quality initiatives and other non-price competition and would suffer from diminished choice.

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[4] 76 Fed. Reg. 21895.

[5] The Innovation Center within CMS may engage in programs that are more ambitious in the tools utilized. The Policy Statement does indicate that "[t]he analytical principles underlying this Policy Statement would also apply to various ACO initiatives undertaken by the Innovation Center . . . so long as those ACOs are substantially clinically or financially integrated." *Id.*¸n. 8. While the potential benefits from more transformative activities may be greater, the potential for harm from enhanced market power remains very much the same. Therefore, the same concerns, analysis, and recommendations reflected in these comments would apply to ACOs participating in Innovation Center initiatives.

Most directly for the Shared Savings Program, the accumulation or inappropriate exercise of market power by Program Participants would subvert the very goals of the Program itself, as well as broader transformative goals of which it is a component. From the perspective of the Medicare program and its beneficiaries, the Program is a means of achieving better quality and efficiency through provider collaborations that coordinate care, manage population health, and otherwise address problems associated with provider fragmentation. If the improved "results" achieved by the Shared Savings Program are simply innovations in accounting, resulting from increased cost shifting from Medicare to commercial patients, rather than innovations in care delivery, the Program will not achieve its goals.

The costs created by these impacts would be compounded by the likely duration of the competitive harm. Market power tends to endure in a manner that is not constrained by the end of the program, changes to funding, or redirection of agency priorities. Indeed, market power is likely to outlast a succession of programs. Therefore, it is critical that HHS do exactly what it has done: draw upon the expertise of the Agencies in addressing competition issues. Further, it is important that the Agencies do what they have done: set forth a process that is efficiently aligned with the Program, while minimizing the risks that the Program will lead to consumer harm through the creation or inappropriate exercise of market power. The question, appropriately raised by the Agencies, is "whether . . . the guidance in the proposed Policy Statement should be changed in any respect?"[6]

The answer to this question is that the Policy Statement should be modified in several respects to more fully protect consumers and ensure the Program fulfills its goals. The Policy Statement creates a good framework, but does not yet strike the appropriate *balance* necessary to ensure that the program realizes its *potential benefits for Medicare beneficiaries*, while reducing its *risk of harm to such beneficiaries and to commercial patients*. We offer specific suggestions for modification of the Policy Statement below.

[6] 76 Fed. Reg. 21900. The Agencies also ask "why" the guidance should be changed. *Id.* Below we explain both what we believe should be changed and why it is important for consumers and for the goals of the Shared Savings Program that these changes be made.

III. *Modifying the Policy Statement in Several Areas Will Help it Achieve the Right Balance Between Providing Guidance and Efficient Process for the Shared Savings Program while Preventing Harm to Consumers*

The Policy Statement is, itself, untested. As indicated above, it creates a good framework, based on appropriate considerations, but the tools that it uses—most notably Primary Service Areas (PSAs)—are new to antitrust analysis and thus there is not a record to judge their effectiveness as part of a screening process. At AHIP's request, Cory Capps, Ph.D. of Bates White attempted to apply the process set forth in the Policy Statement and concluded that the proposed calculations are feasible, given appropriate data. His analysis did reveal several potential issues, which are flagged below in our recommendations for modification of the Policy Statement. In addition, his analysis was limited to hospital inpatient services, because data for the other services are not currently available.[7] This limitation is one reason for our final recommendation that the Policy Statement be subject to evaluation and review over time, to ensure that it is protecting consumers from the harms that accompany provider market power, while providing guidance and efficient process for review.

Thus, informed by this study and other considerations, we suggest that the efforts embodied in the Policy Statement to prevent consumer harm from provider market power, while facilitating potential benefits from the Shared Savings Program through guidance and efficient process, would be enhanced by modification of the Policy Statement in the following areas:

- The Policy Statement should be made more complete in its application to account for some transactions that may otherwise not be reviewed and for material changes in Program Participants;

- The thresholds utilized in the Policy Statement for safety zone treatment and mandatory review should be lowered to more accurately reflect and address the likely harm that will follow from insufficient review;

[7] *See* 76 Fed. Reg. 21899 ("For physician services, the ACO applicant should calculate its shares of Medicare fee-for-service allowed charges (i.e., the amount that a provider is entitled to receive for the service provided) during the most recent calendar year for which data are available. For outpatient services, the ACO applicant should calculate its shares of Medicare fee-for-service payments during the most recent calendar year for which data are available. CMS will make public the data necessary to identify the full range of services and the aggregate fee-for service allowed charges or payments for each service, by zip code.")

- The Policy Statement should indicate explicitly that when a Program Participant is a member of a provider system, PSA calculations should reflect the share of the provider system in the PSA, rather than the share of the individual provider;

- The Policy Statement should give Program Applicants the option of moving directly to the review contemplated by the mandatory review process, rather than first using the PSA-based screening process;

- The Policy Statement should give program participants wishing to demonstrate their desire to avoid market harm a fuller chance to evidence their intentions by adding to and clarifying the list of conduct to avoid;

- The Policy Statement should provide for the Agencies to obtain aggregated information about the impact of the Shared Savings Program on cost shifting from Medicare to commercial patients; and

- The Policy Statement should build in a process of evaluation and review to allow for improvement of the analysis, as well as the data utilized, over time.

Below is more detail on each type of modification suggested.

A. The Policy Statement Should be More Complete in its Application

i. *Program Applicants Should be Subject to the Policy Statement, or Some Other Antitrust Review, Regardless of the Type of Transaction by Which They Were Formed*

As discussed above, the Policy Statement utilizes a "screening" mechanism to determine which Program Applicants will receive fuller antitrust review and which seem unlikely enough to raise anticompetitive issues to make such review unnecessary. The decision to utilize such a mechanism reflects a determination as to the role that the Agencies will play with respect to the Shared Savings Program. The Agencies could have opted from a spectrum of possible approaches, with one end of the spectrum reflecting a statement by the Agencies that they will continue to enforce the antitrust laws in the manner that they generally do. This process works

well in a variety of industries, in a variety of contexts, *including with respect to ACOs that have formed, or are forming, to serve commercially insured populations.*[8] At the other end of the spectrum, the Agencies could indicate that they will perform a detailed review of each Program Applicant, ultimately indicating to the Program Applicant, and to CMS, the outcome of its review. This would involve gathering enough information to define relevant antitrust markets, identify and test theories of harm, and make a judgment on the litigation prospects of bringing an enforcement action.[9]

Between the two ends of the spectrum is the screening process selected by the Agencies. This process does not, however, apply to all Program Applicants.[10] Specifically, it does not appear to apply to two categories of Program Applicants:

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[8] Under this approach, entities forming for purposes of participating in the Shared Savings Program have no obligation to notify the Agencies (unless the transaction is reportable for some other reason, such as Hart-Scott-Rodino reporting requirements for mergers), and the Agencies will investigate and enforce the antitrust laws as they normally do. In such a situation, an entity will typically receive its "guidance" from private legal counsel, informed in part by Agency actions and statements, of the antitrust risks associated with any particular venture. Entities also can seek Agency guidance with respect to prospective activities by requesting an advisory opinion from the Federal Trade Commission or a business review letter from the Department of Justice.

[9] Each end-of-the-spectrum approach has attributes and drawbacks. The first approach does not provide much agency guidance and information, but does not slow the application process and relies upon time-tested agency approaches. The second approach provides much more guidance, but is likely to be time-consuming for applicants, and highly-resource consuming for the Agencies. We recognize that, given the nature of the Shared Savings Program and its likely impact on commercial markets, the first option may prove unpalatable to some stakeholders. We similarly recognize that the second option likely is not realistic, given the anticipated number of program applicants, the requirements of review, and the timing of the Program.

[10] The selected approach has more to commend it than simply not being the first two. It offers guidance to potential Program Applicants, as some have requested. In addition, it simplifies their task of analysis, by using a generalized methodology and information that is or will be available, so that entities can more easily perform their own antitrust analysis. The approach also provides the Shared Savings Program with a quick and efficient process of antitrust review. Even the most intensive level of review will be completed within ninety days of the submission of information, which is much faster than comparable antitrust reviews. Most importantly, it can—with the modifications recommended—protect consumers from creation, enhancement, or inappropriate exercise of market power through the Program, including through a framework for the Agencies to prevent certain entities from participating in the Program based on the likelihood of harm to consumers.

- First, it does not apply to merger transactions, which will continue to "be evaluated under the Agencies' *Horizontal Merger Guidelines*" and many of which will be subject to the notification requirements of the Hart-Scott-Rodino (HSR) Act.[11]

- Second, it does not appear to apply to Program Applicants that are formed through a means other than "collaboration."

With respect to Program Applicants formed through merger, it is logical that the Policy Statement not reach entities already subjected to review under the HSR Act, which provides for data submission and review within a designated timeframe. Not all mergers are subject to review under the Act, however (e.g., mergers that do not meet the size of person or size of transaction tests). Therefore, we recommend that the Policy Statement explicitly apply, in addition to its current scope, to merger transactions that are not reportable under the HSR Act. This will avoid the unintended consequence of having potentially anticompetitive transactions through which Program Applicants are formed not "screened" under the HSR process or the Policy Statement process.[12]

It is unclear whether there could be Program Applicants formed through means other than collaboration or merger agreement. The Policy Statement indicates that "a 'collaboration' comprises a set of agreements, other than merger agreements, among otherwise independent entities jointly to engage in economic activity, and the resulting economic activity."[13] Program Participants may be the ultimate result of a variety of types of arrangements (e.g., mergers, joint ventures, employment), and the Program and consumers will be ill-served if certain types of transactions are viewed as a means of avoiding review. Thus, we recommend that the Policy Statement avoid any potential unintended loopholes by explicitly applying to Program Applicants regardless of the type of transaction through which they were formed, unless the transaction was subject to review under the Hart-Scott-Rodino Act.

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[11] 76 Fed. Reg. 21895.

[12] While we do not propose to set forth the specific means through the Agencies will determine what mergers, not reportable under the HSR Act, should be reported under the Policy Statement, we believe that the Agencies can draw from existing frameworks, such as the transaction aggregation process used under the HSR rules.

[13] *Id.*, n. 10. *(quoting* U.S. Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for Collaborations Among Competitors* § 1.1 (2000), *available* at http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf).

ii. *All Program Applicants Should be Subject to Renewed Policy Statement Analysis and Potential Antitrust Review Based on Any Changes to their Composition During the Program*

Program Participants are prohibited from adding ACO "participants" during their three year agreement to participate in the Program, but the Program Participants are allowed to remove *or add* ACO "providers/suppliers."[14] This appears to reflect a desire to keep the ACO itself (as defined by its participants) essentially the same during its time in the Program, while recognizing that the ACO's participants (e.g., physician groups, hospitals) may themselves have turnover (e.g., physicians leaving and joining a group physician practice). In a number of possible situations, however, the application of this rule could raise antitrust concerns, essentially allowing a Program Participant to add, either at once or over time, physicians, hospitals, or others to a degree that creates market power and undermines the review process.[15]

Therefore, it is crucial that the Agencies have the ability to conduct a new analysis and review of Program Participants at any time during their participation in the Program. Both CMS's proposed rule related to the Program and the Policy Statement contemplate re-review by the Agencies in some circumstances, but the re-review also appears to be limited to certain situations.[16] In addition to its current statements related to changes to the Program Participants, the Policy Statement should explicitly indicate the following:

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[14] *See* proposed 42 CFR § 425.21(a)(1). We note that this provision of the proposed rule may have unintended consequences as written, potentially advantaging certain ACO structures over others. Because this may have competition-related implications, we suggest that the Agencies discuss this provision with CMS.

[15] The concerns are similar to those that underlie the transaction aggregation process used under the HSR rules.

[16] Thus, proposed 42 CFR § 425.5(d)(2) requires an ACO to provide CMS with 30 days prior notice of "***any material change***" to a Program Participant's ACO participants or ACO provider/suppliers and submission of recalculated PSA shares for common services. If any revised PSA share is calculated to be greater than 50% [40% if the recommendation in this letter is accepted], the ACO will be subject to review or re-review by the Agency. If the reviewing Agency gives the Program Participant a letter stating that the Agency will likely challenge or recommend challenging the Program Participant, the Program Participant will be *ineligible to participate* in the Program. 42 CFR § 425.5(d)(2). (emphasis added).

The Policy Statement indicates that "[t]he safety zone will remain in effect . . . unless there is a ***significant change*** to the ACO's provider composition." 76 Fed. Reg. at 21897 (emphasis added). It also indicates that an ACO must seek antitrust review if there is a "***significant change*** to the ACO's provider composition such that the ACO

- the Agencies may conduct a re-review of the eligibility Program Participants; and

- Program Participants should notify CMS and the Agencies of any changes—whether through contract, acquisition, employment, or otherwise—that would materially increase their PSA shares, including but not limited to, changes to physicians, other health care professionals, hospitals, other facilities, and physician groups.

B. The Thresholds Utilized in the Policy Statement Should be Lowered to More Accurately Reflect and Minimize the Total Likely Costs to Consumers from Screening Error

The use of a threshold-based screening process seems an appropriate way to meet the dual goals of "ensuring that providers have the antitrust clarity and guidance needed to form procompetitive ACOs," while utilizing an analytical framework that is "sufficiently rigorous to protect both Medicare beneficiaries and commercially insured patients from potential anticompetitive harm."[17] Further, the use of a screening process both has precedent (in the HSR context) and is consistent with the concept that underlying antitrust law and principles are unchanged by PPACA, in general, and the Shared Savings Program, in particular. Because the thresholds determine the rigor of review, however, it is important that they be set at levels that minimize the likely harm from "screening error."

Errors from the threshold-based screening process can be divided into two categories. First, there is the error of overinclusiveness, meaning that there will be review (or the option of review) of some entities that do not merit such review because they are unlikely to lead to competitive harm. Second, there is the error of underinclusiveness, meaning that there will be no review (or no mandatory review) of some entities that do merit such review because they have the potential to lead to competitive harm. Because the approach of analyzing entities based on PSAs is a new endeavor, it is hard to know whether the Policy Statement's tiers of 0-30%, 30-50%, and 50-100% are more likely to be, in total, more overinclusive or underinclusive.

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exceeds the 50 percent threshold or is ***materially different*** from what was initially reviewed." *Id.* at 21898, n.36 (emphasis added).

[17] 76 Fed. Reg. at 21896.

There is some reason, however, to be concerned that the framework set forth in the Policy Statement may—in certain circumstances—under-reflect the potential market power of a type of entity. Specifically, the analysis performed by Dr. Capps suggests that an entity with a strong reputation, for example based on academic medical center status, may be more likely to have a larger PSA, resulting in smaller shares within the PSA, even thought an area smaller than the PSA may be a more realistic area within which market power could be exercised. Because such entities may well be the very types of "must have" providers that raise significant market power concerns, a screen that did not lead to review of Program Applicants including such providers would be underinclusive in a way likely to be harmful to consumers.

More generally, the scope of likely harm to consumers from an instance of underinclusiveness is likely to be much more significant than the scope of likely cost from an instance of overinclusiveness. Each time the operation of the Policy Statement is underinclusive, i.e., it allows the formation of an entity with market power without sufficient review, it creates the risk of market harm. The newly formed entity will, in all likelihood, operate in commercial and Medicare markets and thus can exercise its market power directly in a variety of ways, including in the form of higher prices for commercially-insured patients. In contrast, each time the operation of the Policy Statement is overinclusive, it simply subjects an entity to some additional level of review, conducted within ninety days. Thus, the potentially significant harm to consumers from even a small amount of underinclusiveness is likely to dwarf the modest cost from a good deal of overinclusiveness.[18]

This, combined with the new and untested nature of the screening analysis to be utilized, suggests that the Agencies should use lower thresholds, subjecting relatively more entities to more rigorous, but still relatively quick, review. Again, the approach proposed by the Agencies, and the revisions suggested here, apply only to the screening process used by the Agencies in the unique context and needs of the Shared Savings Program. Not only is substantive antitrust law necessarily unchanged, but the screening process does not, and should not, replace the Agencies' typical approach to antitrust review in other contexts.

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[18] CMS estimates that the Shared Savings Program will generate about $510 million in savings for the federal government over three years. This stands in contrast with the total operating revenues for hospitals in one medium sized city of over $7 billion. When a price increase with respect to such services is multiplied over many jurisdictions over those three years, the savings could assume the level of noise when compared with the harm. *See* Miller, Joe, *The Proposed Accountable Care Organization Antitrust Guidance: A First Look*, HEALTH AFFAIRS BLOG (2011), *available at:* http://healthaffairs.org/blog/2011/04/14/the-proposed-accountable-care-organization-antitrust-guidance-a-first-look/.

The specific context of the Shared Savings Program leads to two specific recommendations:

i. The Safety Zone Should Utilize a Threshold that Minimizes Screening Error and is Consistent with Past Agency Differentiation Between Exclusive and Non-Exclusive Arrangements

First, the risk of harm is greatest with respect to the application of a "safety zone." The Agencies will not, absent extraordinary circumstances, challenge Program Applicants that fall within the safety zone, and such entities "have no obligation to contact the Agencies."[19] While not stated, it appears that the 30% level may have been chosen in relation to the safety zone for *non-exclusive* financially integrated physician network joint ventures that the Agencies set forth in Statement 8 of the 1996 Statements of Antitrust Enforcement Policy in Health Care ("1996 Guidelines ").[20] The same statement, however, includes a threshold of 20% for *exclusive* financially integrated physician network joint ventures, reflecting a decision to subject a greater percentage of exclusive, rather than non-exclusive, physician network joint ventures to more careful scrutiny.[21]

It is important that the differentiation made between exclusive and non-exclusive arrangements in the 1996 Guidelines also be considered here. In particular, the Shared Savings Program as outlined in the NPRM requires primary care providers to participate in an ACO for Program purposes on an exclusive basis.[22] However, as currently drafted, the Policy Statement's safety

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[19] 76 Fed. Reg. 21897.

[20] U.S. Dep't of Justice & Fed. Trade Comm'n, *Statements of Antitrust Enforcement Policy in Health Care* (1996) *available at:* http://www.justice.gov/atr/public/guidelines/0000.pdf.

[21] Indeed CMS has recognized the potential additional concerns that can arise with respect to exclusive arrangements in the Shared Savings Program, noting that "reducing the number of specialists that can participate in one ACO" could "undermine our goal of ensuring competition among ACOs." CMS, *Notice of Proposed Rulemaking, Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations* (2011), 76 Fed. Reg. 19528, 19565 ("CMS Rule").

[22] *See, e.g.,* CMS Rule at 19563 ("We also propose that ACO professionals within the respective TIN on which beneficiary assignment is based, will be exclusive to one ACO agreement in the Shared Savings Program. This exclusivity will only apply to the primary care physicians (defined as physicians with a designation of internal medicine, geriatric medicine, family practice, and general practice, as discussed in this rule) by whom beneficiary assignment is established.") While this requirement of exclusivity may be necessary for the Program, based on the Program's approach to beneficiary assignment, it is not necessary in commercial markets. It may well have competitive implications in commercial markets, however, similar to those described by CMS with respect to specialists, and these implications are a necessary and important part of Agency analysis.

zone applies to entities regardless of whether participating physicians are exclusive or non-exclusive to the ACO. Given that the NPRM requires primary care physicians to participate in ACOs operating under the Program on an exclusive basis, past Agency practice suggests that 20% would be a more appropriate and consistent threshold for screening purposes. Moreover, building on the logic of the screening process, its precedent, and the new and untested nature both of the Shared Savings Program and the process embodied in the Policy Statement, utilizing a 20% screening threshold rather than 30% will reduce the likelihood that the safety zone will generate significant consumer harm by not submitting enough entities to any review.

ii. Mandatory Antitrust Agency Review Should Similarly Utilize a Threshold that Minimizes Screening Error

A similar logic applies with respect to the threshold for mandatory Agency review. Entities subject to such review may be able to participate in the Shared Savings Program, but an appropriate understanding of their likely competitive impact requires a more careful look than allowed under the first step of the screening process. Including entities in the range of 40-50% in the mandatory category reduces the possibility that the Policy Statement will enable the establishment of entities with the market power to the detriment of consumers.

C. The Shares Utilized in the Policy Statement Should Account for System Membership of Program Participants

A significant portion of the provider consolidation referenced at the beginning of this letter has resulted in the creation of systems of multiple hospitals and other providers with market power. This has resulted in harm to consumers through higher prices, lower quality, and reduced innovation. Antitrust analyses typically, and correctly, treat such systems as one entity for purposes of calculating shares. The Policy Statement, however, does not explicitly indicate how to treat other locations owning, owned by, under common ownership with, or in a system with a Program Participant. The Policy Statement may address this point in its discussion of "participants" as "independent" entities, but—given the significance of the issue—the point should be made more explicit. The approach should be consistent with that typically utilized by the Agencies, and thus the "shares" should reflect the share of the entire system.

D. The Policy Statement Should Give Program Applicants the Option of Moving Directly to the Review Contemplated by the Mandatory Review Process

Some potential Program Applicants have raised concern about the cost of providing PSA-related information when they know that they are highly likely to have to undergo the mandatory review

process. Since the PSA process operates as a screen to help the Agencies determine when a fuller review is warranted, it does not seem necessary to engage in this process when entities inform the Agencies that they believe they would fall into a category in which review would be mandatory, or optional, and would prefer to proceed directly to the fuller analysis contemplated by mandatory review. This will serve the interests of all involved by relieving applicants of some burden and allowing the Agencies to receive, and review, the information most relevant to their analysis earlier in the process, and therefore to provide earlier guidance to the potential Program Applicants and CMS.

E. The Policy Statement Should Give Program Participants Wishing to Demonstrate their Desire to Avoid Market Harm a Fuller Chance to Evidence their Intentions

The Policy Statement gives entities that fall between the safety zone and mandatory review the ability to "reduce significantly the likelihood of an antitrust investigation" by avoiding five categories of conduct.[23] The Policy Statement indicates that "avoiding the first four categories of conduct is important to facilitate payers' ability to offer insurance products that differentiate among providers based on cost and quality."[24] Avoiding the fifth type of conduct "ensures that the ACO does not facilitate collusion involving ACO participants that contract with payers outside of the ACO."[25] As a preliminary matter, we believe that the Policy Statement should indicate that the list is being offered for illustrative purposes, rather than to create a checklist-driven "safety zone." Innovations in anticompetitive practices are no less likely than innovations in procompetitive practices, and the Agencies and consumers will be ill-served if the Agencies are hamstrung in their ability to remedy newly developed or recognized approaches to the exercise of market power.

We do believe, however, that this guidance reflects an important recognition of the many ways in which market power can lead to harm to consumers beyond price increases. Indeed, as health insurance plans continue to engage in various initiatives to offer consumers quality and cost information to help them make decisions related to their care, the conduct that the guidance seeks to deter could substantially undermine such efforts. Therefore, we support the list included in the Policy Statement, with some modifications to the items. In addition, we offer two additional

[23] 76 Fed. Reg. 28198.

[24] *Id.*

[25] *Id.*

items for inclusion in the list: one of which similarly seeks to deter conduct that could harm consumers and one of which ensures that the Agencies are able to obtain the information necessary for assessing the impact of the Shared Savings Program.

Specifically, we suggest the following changes to items on the list.

- **With respect to the first item (*relating to "anti-steering" and related restrictions*) and the third item (*related to exclusivity*), making it clear that exclusivity and other restraints may be present explicitly or implicitly, formally or informally, through written agreement or in a *de facto* manner.** Because of the reference to "contractual clauses or provisions" and "contracting" (in contrast with the second item, which references "explicitly or implicitly"), we are concerned that some could misconstrue the Agencies' likely intent as extending only to formal, written provisions. We believe that clarifying these provisions will help prevent such misunderstandings and preserve the underlying intent of addressing the conduct, regardless of its form.

- **With respect to the fourth item (*relating to restrictions on plan efforts to make information available to enrollees on cost, quality, efficiency, and performance*), remove the clause "if that information is similar to the cost, quality, efficiency, and performance measures used in the Shared Savings Program."** Consumers are harmed when they are unable to get information on provider cost, quality, efficiency, and performance, whether or not the measures are those used in the Shared Savings Program, and all such restrictions should be disfavored.

- **With respect to the fifth item (*relating to sharing among the ACO's provider participants competitively sensitive pricing or other data that they could use to set prices or other terms for services they provide outside the ACO*), broadening the provision to also prohibit such sharing to the extent the ACO participants are not sufficiently clinically or financially integrated outside of the Program.** Although there is good reason to believe that Program Participants will use the same structures for commercial patients that they use with respect to the Program, the requirement of clinical or financial integration should not be obviated by Program participation itself.[26]

[26] On a related note, we suggest that those who have indicated that the clinical integration "requirements" of the Program be reduced, or that financial integration analysis be used instead, are letting the "tail wag the dog." The Shared Savings Program has established requirements that CMS has determined to be necessary for the delivery of

We also suggest the addition of the following items to the list:

- **A prohibition on explicitly or implicitly using hospital admitting privileges in a manner harmful to competition.**

- **An affirmative commitment to provide the Agencies with all information they request to allow them to assess the market impacts of the Program Participant's creation, operation, and participation in the Program**. Specifically, the commitment would be to "Provide the Agencies with all information that the Agencies determine is necessary to allow them to assess the impact of the entity and/or its participation in the Shared Savings Program on competition issues."

F. The Policy Statement Should Provide for the Agencies to Obtain Aggregated Information about the Impact of the Shared Savings Program on Cost Shifting from Medicare to Commercial Patients

The Shared Savings Program should not allow Program Participants to obtain shared savings payments by reducing Medicare expenditures and compensating for the reduced revenue by exercising market power in the commercial market. CMS's rules governing the Shared Savings Program should allow it to gather information to determine whether such cost shifting is occurring and terminate the participation of Program Participants that are engaging in cost shifting.

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higher quality, more efficient care to beneficiaries. The Agencies then determined that these were "broadly consistent with the indicia of clinical integration that the Agencies previously set forth in the Health Care Statements and identified in the context of specific proposals for clinical integration from health care providers." 76 Fed. Reg. 21896.

Over time, the Agencies have appropriately resisted calls to define in a detailed fashion (and therefore channel, chill, or limit) the activities that constitute clinical or financial integration. Rather, they have provided principles of general application and used them to determine the antitrust implications of specific activities in specific contexts. This is what they have done here with respect to clinical integration and this approach should not be modified. Nor should some notion of the "bare minimum" for clinical (or financial) integration under antitrust analysis be used to abrade the specific goals and requirements of the Program.

The Agencies should have a role in this Process, and the Policy Statement should be modified to reflect this. CMS is gathering cost, quality, and utilization data to test whether the Program's eligibility criteria in fact further program goals. CMS should share with the Agencies aggregated cost and utilization information related to possible cost-shifting by Program Participants. This aggregated information should include, for each Program Participant: (1) Medicare total costs for assigned beneficiaries and (2) total costs for all populations receiving care in the ACO.

G. The Policy Statement Should Build in a Process of Review and Analysis to Allow for Improvement Over Time

The Policy Statement has certain limitations because of the newness of not only the Statement itself, but of the Shared Savings Program to which it relates. At least some of these limitations, however, may not persist over time. For example, as noted above, the analysis performed by Dr. Capps was limited to inpatient hospital services, in part because the Medicare data that will be used to perform the physician services analysis is not yet available. One question that cannot be answered until that data becomes available is how well the Medicare-only data serves as a proxy for market power issues faced by commercial patients. This issue may be particularly acute with respect to physician services, given the greater likelihood of physician practices with very high percentages of commercial patients and low percentages of Medicare patients.

To assess whether the Policy Statement can be improved, the Agencies should develop a framework for reviewing and analyzing the effectiveness and impact of the Policy Statement during the operation of the Shared Savings Program. This could include the following three categories of activities:

- **Assessing the Test:** The Agencies should examine how the screens are working, including the critical question of whether they are leading to insufficient review of entities that are likely to have market power.

- **Assessing the Data:** The Agencies also should evaluate how well the data used reflect actual market dynamics, and what impact this has on whether entities likely to have market power are subject to sufficient review (e.g., because Medicare-only data may not adequately reflect the market power of entities more focused on commercial markets). In addition, the Agencies should consider, over time, whether new sources

of data can be used to supplement or replace the data sources set forth in the Policy Statement.

- **Assessing the Participants:** Of course, the most direct evidence of *market impact* will come from examining the *impact on markets*. In engaging in this examination, the Agencies should examine the data provided to them by CMS, Program Applicants, and Program Participants to understand whether and how much Program Participants have increased prices in commercial markets or taken other actions that harm or benefit commercial patients.

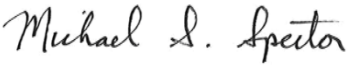
The Agencies should use the results of their analysis not only to refine the Policy Statement, but to inform themselves, other agencies, and stakeholders as they consider other efforts that fall at the intersection of health care and antitrust. In particular, the market analysis reflected in the third bullet may help stakeholders better understand ways in which efforts to transform the health care delivery system can benefit consumers, ways in which such efforts can harm consumers, and ways to better assess, in advance, which efforts are most likely to lead to which outcomes.

Conclusion

Thank you for your consideration of our comments on these important issues. Please feel free to contact us with any questions you may have about our comments and recommendations. We stand ready to work with the Agencies to help ensure that the natural alliance between the goals of the Shared Savings Program and those underlying the antitrust laws is most fully, and effectively, realized to the benefit of consumers.

Sincerely,

Joseph M. Miller
General Counsel



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