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M E M O R A N D U M

To: Federal Trade Commission/Department of Justice

From: Jam es Langenfeld, PhD and Tracey L. Klein

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Subject: Comment regarding the Proposed Policy Statement regarding Accountable Care Organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP)

I. Introductio n

The FTC and DOJ structured approach to evaluating the antitrust implications of ACOs is in general reasonable, but there are certain aspects of the proposed review process that could discourage efficient ACOs from forming. In particular, the review process as currently outlined in the "Proposed Policy Statement" (the "Statement") has the potential for imposing an additional layer of complexity to the other aspects of qualifying as an ACO under ACA, potentially resulting in substantial costs and delays, even for efficient and pro-consumer ACOs. The Statement also appears to impose too strict requirements for avoiding Agency review. Accordingly, the Statement may limit the ability of ACOs to develop distinct pro-competitive product offerings and may even discourage the formation of efficient and pro-consumer ACOs. Our comments below are intended to identify certain aspects of the Statement that tend to reduce the regulatory burden and others that could substantially increase the burden, and to offer some suggestions for modifying the Statement to lessen the burden and increase clarity.

II. General Clarifications to Reflect Current Law

The FTC and the DOJ are proposing enforcement policy regarding the application of antitrust laws to health care collaborations among otherwise independent health care providers that seek to participate (or otherwise have been approved to participate) as

ACOs in the MSSP. The Agencies recognize that ACOs generate opportunities for health care providers to integrate in both the Medicare and commercial markets. In fact, recent commentary from the Agencies suggests that they believe health care providers are more likely to integrate if they can also use ACOs for commercial patients. This viewpoint seems to acknowledge that significant resources will be required on the part of providers to form ACOs, and that there is a need to eliminate fragmentation in the health care delivery system.

In instances where a CMS-approved ACO provides the same (or essentially the same) services in a commercial market as in Medicare, the Agencies state the CMS integration criteria are sufficiently rigorous that joint negotiations with private sector payers are reasonably related to the ACOs' primary purpose of improving health care services. To qualify for treatment as a potentially acceptable ACO for commercial products under the Statement, the ACO must use the same governance, leadership structure, and clinical and administrative processes as it uses in the MSSP.

Previously, representatives of the FTC have expressed in public that price fixing concerns do not exist for independent providers collaborating to form Medicare ACOs because the government sets the rate. However, the Statement does not say this explicitly. It would be helpful for certain ACOs if the Statement would clarify the impact of the antitrust laws on ACOs that form for the sole purpose of participating in the MSSP and do not contract in commercial markets.

The Statement was developed to expedite and clarify antitrust analysis and processes as it applies to collaborations among otherwise independent providers and groups that seek to participate in the MSSP. While current law provides price fixing and market allocations among competitors are treated as per se illegal, arrangements involving competing providers that are financially or clinically integrated are analyzed under a "rule of reason". The Statement appears to expand the ability of independent providers to collaborate to develop joint products by stating that CMS' proposed eligibility criteria for ACOs are broadly consistent with the indicia of clinical integration, thereby qualifying such arrangements for a "rule of reason" analysis. The Statement should more clearly state that financial risk sharing (i.e., capitation) will also allow

collaborations among independent providers to be analyzed under the "rule of reason" in that many providers who participate in the MSSP or other efforts to develop ACOs will necessarily be financially integrated.

III. Definition of Geographic Market and Primary Service Area

The Statement provides some clear market share benchmarks for “safety zones” for independent providers or provider groups that seek to participate, or have otherwise been approved to participate, in the MSSP. It indicates that independent ACO participants that provide common services must have a combined share of 30% or less in the "Primary Service Area" (PSA) to qualify for "safety zone" protection. The Statement acknowledges that while a PSA does not necessarily constitute a relevant antitrust geographic market, PSAs can be a useful tool for screening out ACOs that have little or no likelihood of creating adverse competitive effects.

PSA is defined as the lowest number of contiguous postal zip codes from which the ACO participant draws at least 75% of its patients. This approach seems to underestimate the complexity of determining the geographic markets in the health care industry. While much of health care is still local in nature, Medicare beneficiaries can and do travel outside of their local communities, regionally and nationally for health care services.

The benchmark of 30% share for the safety zone that allows the ACO to avoid Agency review, but depends critically on the overlapping services and geographic areas served by the members of the ACO. Many antitrust investigations involve extensive and detailed analyses of product and geographic market definition. To the Agencies’ credit, the Proposed Statement offers systematic ways to simplify share calculations based on systematic calculations of the relevant geographic area based on patient flow data (75% patient draw area) and established service reporting lines (such as MSCs). The use of these benchmarks and market definition methodology should help make the implementation of the review clearer and more predictable for potential ACOs. As Fisher and Lande describe the importance of efficient and predictable review of mergers:

> [C]ommentators have emphasized what we call Type 1 and Type 2 error; that is, stopping beneficial mergers and allowing undesirable mergers. However, merger policy can make a third type of error. Type 3 error occurs when compliance with merger policy creates excessive cost to business, enforcers, and decision makers. Quantitatively it is very significant, and any policy that ignores its runs substantial risk of departing from an optimal social result.[1]

An antitrust review of an ACO is similar to reviewing a merger, and minimizing Type 3 error is particularly important here since the ACA encourages the creation of ACOs to aid in reducing health care costs. However, there are some cautions related to this approach for defining safety zones.

First, the Statement should explicitly indicate that a small overlap should not trigger a full review, even in the 30-50% range. MDCs, for example, typically have several DRGs. Two potential members of an ACO may have little or no direct overlap in services or one may have very few patients in the MDC while the other has many, but the Statement would require that the ACO submit for review if the two together had 50% or more of the MDC. The same concern occurs with regard to minimal overlap in the geographic area screen. We suggest that the Statement clearly indicate that an ACO should quality for the safety zones if members present only a very minor competitive overlap. For example, if there were two members of the ACO that overlapped in an MDC where they collectively had 40%, but one had 39.5% of the MDC in the PSA and other had 0.5%, then the ACO would treat them as not meaningfully competing and therefore not in need of a review.

Second, an overly narrow definition of PSA may add an obstacle to the creation of pro-competitive ACOs. In non-integrated health care delivery systems, it may be difficult to ensure that independent ACO participants (i.e., physician group practices) that provide common services (and in the case of primary care physicians are responsible for the provision of care to 5,000-10,000 Medicare beneficiaries) have a combined share of 30% or less in PSAs as defined by the Statement . To form and survive, ACOs may need

[1] Alan Fisher & Robert H. Lande, Efficiency Considerations in Merger Enforcement, 71 Calif L. Rev. 1580 (1983) at 1670-77. (footnotes omitted)

to go beyond mirroring the current local health care delivery system, and compete on a broader regional basis where they would not have a large enough share to create competitive problems. Accordingly, the Statement would benefit from explicitly stating that approval will be likely be given to ACOs that can show a credible plan for expansion even if they fall into the 30% to 50% share range based on current patient flow data.

IV. Impact on Limitations on Exclusive Contracts

The Statement requires that hospitals and/or ambulatory surgery centers (ASCs) must be non-exclusive to the ACO to be included within the safety zone, regardless of PSA share. Non-exclusivity in this context means that hospitals and/or ASCs that join ACOs must be allowed to contract with other ACOs or commercial payers independently. If combined share of common services is less than 30% in the PSA, physicians can be exclusive or non-exclusive. The emphasis on non-exclusive contracts for hospitals (and with physicians outside the safety zone) may inhibit the coordination and alignment that must occur to redesign health care. ACOs may be crippled in their efforts to manage population health because both physicians and patients will be necessarily free to move between ACOs without restriction.

It is unrealistic to believe that any ACO would likely be effective without the possibility of physician specialists and hospitals being able to engage in exclusive contracts. This is particularly true for the 30-50% range of combined share of the ACO participants, where the threat to competition, in general, will not be significant.

V. Minimization of Antitrust Review

Lastly, the opportunity created by the Statement to request permissive antitrust review for ACOs below the 50% mandatory review threshold may actually create an obstacle to ACO formation. Many ACOs may view the invitation to request a review as an actual requirement, and as such will increase costs and delays associated with forming an ACO. The Statement should provide broad safety zones (below the 50% mandatory review threshold) that permit pro-competitive ACO formation and minimize the necessity for Agencies' review.

IV. Conclusions

1. The Policy Statement should clarify existing law.
    - Price fixing does not occur for CMS ACOs when government sets the rate.
    - Financial risk sharing (i.e., capitation) is sufficient to establish "rule of reason" analysis outside the context of the safety zones.
2. The concept of PSA allows for simple calculations of geographic market share, but need more clarifications to minimize investigations a minor overlaps and the importance of market expansion.
3. ACOs may need to utilize exclusive contracts with hospitals and physicians in order to develop pro-competitive product offerings, and therefore should not be given too much weight in evaluating the competitive effects of an otherwise pro-competitive ACO.
4. ACOs below the 50% mandatory review threshold and outside of the safety zone should be given guidance by the Statement, but not necessarily encouraged to request permissive review.

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The opinions are those of the authors, and do not necessarily reflect the opinions of others.