May 31, 2011

The Honorable Christine Varney
Assistant Attorney General
Antitrust Division
United States Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

The Honorable Jon Leibowitz
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Re: Comments on the Federal Trade Commission ("FTC") and Antitrust Division of the Department of Justice ("DOJ") Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations ("ACOs") Participating in the Medicare Shared Savings Program ("MSSP") ("The Policy") (Matter V100017)

Dear Assistant Attorney General Varney and Commissioner Leibowitz:

The Federation of American Hospitals ("FAH") is the national representative of nearly 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay and long-term care hospitals in urban and rural America, and provide a wide range of ambulatory, acute and post-acute services. The FAH appreciates the opportunity to comment upon the proposed Policy regarding the application of the antitrust laws to MSSP ACOs. These comments will be limited to the elements and implications of the Policy itself.[1]

EXECUTIVE SUMMARY

The Policy makes a very significant change to the historical role of the Agencies in their approach to the health care industry, migrating from an enforcement role to that of regulatory agencies. That change places new and unwarranted burdens on those who seek to be responsive to the call for ACOs and the benefits they are perceived to bring to consumers. We also believe that an

[1] The FAH will comment separately on the proposed rule addressing ACO formation and payment under the MSSP (issued by the Centers for Medicare & Medicaid Services ["CMS"]) ("CMS Proposed Rule") as well as a notice with comment period addressing waiver designs in connection with the MSSP (issued by CMS and the Office of Inspector General ["OIG"]).

antitrust analysis (which we recognize has been proposed in a novel, expedited approach) should not be a prerequisite to entering into a MSSP ACO contract.

With regard to specifics of the Policy, we urge the Agencies to abandon the proposed and problematic primary service area analysis, to create greater flexibility with regard to exclusivity restrictions, and to eliminate the mandatory review by the Agencies for what we suspect will be an inordinately large number of potential ACOs. Finally, given the newness of the approach taken, the Agencies should clarify further how the proposed approach to antitrust scrutiny for ACOs will affect other clinical integration and coordination efforts outside of the MSSP ACO framework.

GENERAL COMMENTS

The FAH appreciates and acknowledges the value of the collaborative effort by CMS, DOJ, and the FTC to address the challenges created by ACO formation and operations, as well as the important role played by the stakeholder meeting and other opportunities for public input prior to the Policy being issued. The FAH hopes that this type of collaboration will be continued as cross-over issues continue to arise in the health care field.

I. The Policy Should Be Changed To Reflect the Historic Role of the Agencies and Reduce the Regulatory Burden

The FAH is concerned that the effect of the Policy (in combination with the CMS Proposed Rule) is to move the Agencies from their historic enforcement role to that of regulatory agencies. This role change would be accompanied by a significant shift in the burden placed upon those who wish to enter the market place from one of opportunity to one of sustaining a burden of proof that the Agencies should not use their enforcement powers to challenge an arrangement as anti-competitive. Thus, those who would pursue MSSP ACO status, in a large share of cases, will have to proactively convince the Agencies that the arrangement is unlikely to restrain competition. The health reform legislation did not contemplate such a dramatic shift, and this new approach may have significant policy implications for reviewing future clinical integration arrangements, whether limited to the Medicare program, or if expanded, into commercial markets**. Therefore, the FAH strongly urges the Agencies to revisit the Policy and make changes to align the final Policy with the current antitrust enforcement role that Congress has articulated the Agencies should serve.**

The FAH also believes the Policy should not add undue burden and expense by requiring a mandatory regulatory approval process before the ACO can operate in the MSSP. **The Policy should not be intended to supersede – now or later – the Agencies' current approach to overseeing existing clinical integration arrangements or new arrangements that fall outside the scope of the MSSP.** While the Policy provides limited assurances to this effect, given its fundamentally different approach, it is important for the Agencies to clarify further how they anticipate the Policy will be used now and in the future in reviewing arrangements seeking to clinically integrate providers.

The FAH supports an expedited timeframe for reviewing MSSP ACOs, but more attention to the process is required. The nature of the antitrust review process creates unnecessary risks. As the process indicates, the onus is on the proposed ACO to furnish all the required information, which is very substantial, before the review process is triggered. Then, the process, apparently, will move forward until a determination is made to issue a letter stating either that the reviewing Agency is likely to challenge or recommend challenging the ACO if it proceeds, or that it will not. But a simple "up or down determination" (within an expedited 90-day timeframe) without a

clearly articulated opportunity for an "early warning" with respect to issues of concern and the ability, through negotiation or discussion during the process, to resolve issues, can lead to unnecessary uncertainty, costs, and delay. In addition, the Policy does indicate, in situations where there are competitive concerns which are capable of being addressed, that the Agencies may provide a "remedy," but it offers no indication of the process that will ensue if such a remedy is required.

II. An Antitrust Analysis Should Not Be a Prerequisite to Seeking to Enter into a Medicare MSSP Contract

Requiring an ACO to undertake the Policy's antitrust analysis as a condition precedent to being considered by CMS for a MSSP contract is unnecessary and will be a significant deterrent to forming a MSSP ACO. Medicare sets the prices it pays for services, so the standard antitrust concerns about price-fixing and monopolization as a way to influence market prices and behavior do not exist. Nevertheless, CMS's Proposed Rule would require a prospective ACO to determine its market share under the Policy for purposes of considering whether it needs (or desires) to obtain a private letter ruling from the Agencies that it will not be challenged as illegal. As the Agencies know and appreciate, conducting the Policy's antitrust market review will be a significant undertaking, both in time and resources, and presents an undue burden for those entities seeking to operate as ACOs under Medicare's MSSP program, which is outside the purview of standard antitrust concerns.

We understand the logic that an ACO that operates under the MSSP program also may participate as an ACO with commercial payers, and antitrust issues potentially could arise in appropriate market foreclosure or situations where there has been an inappropriate exercise of market power. However, as discussed below, a policy that <u>requires</u> MSSP ACOs with a 50 percent or greater market share for a particular service line to have to automatically seek prior approval from the antitrust authorities is a significant departure from the historical approach applied by the Agencies for commercial clinical integration arrangements. Again, this change in the Agencies' role and shifting of burden is not contemplated by the health reform legislation, and certainly will chill the desire for many entities to seek to participate in the MSSP program.

We strongly urge the Agencies to recommend that CMS eliminate the requirement for an upfront antitrust review as a condition precedent to an MSSP contract.

III. The Policy Does Not Enhance the Landscape to Encourage ACO Formation

The MSSP ACO program is one of the most highly anticipated delivery reforms in the health reform legislation. At the October 2010 Workshop, top officials from the FTC, CMS, and OIG recognized the need to create sufficient flexibility to allow stakeholders to innovate and deliver health care in new, collaborative ways. However, the opportunity created by the MSSP program, with the overlay of the Policy, is likely to be extremely narrow. It likely does not create a materially enhanced flexibility or encouragement to ACO formation over the existing framework for clinical integration within multi-provider networks, as articulated in a series of FTC Advisory Opinions. (*See, e.g.*, Advisory Opinion, Greater Rochester Independent Practice Association [Sept. 17, 2007], Advisory Opinion, Tristate Health Partners, Inc. [April 13, 2009].)

Our belief is premised on concerns with the Policy's nature of the antitrust review process, the likely results in the markets where the approach will be used, the approach to exclusivity taken, and the other requirements to receive the necessary approval. These antitrust barriers are in addition to the

fact that ACOs will be subject to more onerous and costly requirements of ACO formation under the CMS Proposed Rule.

The Agencies should revisit the Policy and make it more consistent with the goal of establishing a flexible environment necessary to encourage and promote a more innovative and collaborative care delivery system. The Policy should not impede the path to create ACO structures by significantly increasing the upfront investment and imposing a novel analytic approach to measuring and determining market power that is not likely to be supported by a favorable return on that investment, financial or otherwise. Without significant improvements to the Policy as well as the CMS Proposed Rule, we are concerned that interest and commitment from potential ACO stakeholders will be limited.

SPECIFIC COMMENTS ON THE POLICY

I. The Primary Service Area Formula is Problematic and Should Be Abandoned

The Policy offers a new and untested proxy for ascertaining market power. The key determination to be made in the analytical process is whether the Primary Service Area ("PSA") for each group of participants in a common service line is: (1) 30 percent or less; (2) exceeds 50 percent; or, (3) falls between 30 percent and 50 percent. Common service lines that are 30 percent or less receive "safety zone" status for antitrust purposes, while those that exceed 50 percent in their PSAs must seek prior approval from the Agencies. ACOs with PSAs falling between 30 percent and 50 percent are not exempt for challenge by the Agencies, and may request a review by the Agencies if they so desire.

We have several concerns with the PSA analysis. **First, we are concerned that the three-tiered review system is too rigid, and does not provide the necessary flexibility to take into account true market factors that may affect the level and extent of antitrust scrutiny, and thus should be abandoned.** Second, assuming the necessary PSA data are current and available, it is not known whether an approach so dependent on these data is truly a valid substitute for historical antitrust market analysis. This is particularly the case when the PSA share calculations are based solely on the data from Medicare fee-for-service claims. Thus, while offering a "quick look," and thereby providing a framework for a 90-day analysis and conclusion, whether the proposed approach is a true measure of market power is an open question.

Third, there is no clear guidance as to how the Agencies' antitrust analysis will be applied to its review of the PSA determinations and other data required to be submitted. For example, where review is mandated, will the Agencies give consideration to only the competitive environment with respect to the common service line in which the PSA share exceeded 50 percent, or to the Medicare market effects as a whole, or to the overall combined market effects when all lines of business are considered. More generally, a much clearer statement of enforcement principles in this area would be of great value.

We also are concerned that an ACO may not have the data to calculate the PSAs. ACOs will need to collect PSA data from independent and presumably competitive providers who may not be willing to share the data with the ACO. Further, the ACO itself may not have the breakdowns by zip code, and it may not always be clear about the Major Diagnostic Categories a hospital must include in its calculation of the PSAs.

If the Agencies are inclined to continue to use the PSA model, we believe the PSA analysis should be changed to focus on the overall market share of the ACO, and not on individual, common service lines. Initial market analysis of major markets reported by the American Hospital Association, among others, suggests that the likelihood of a PSA over 50 percent in any given market, in at least one service line (which is all that is required to trigger the review) is quite high. Accordingly, the requirement of a mandatory antitrust review and the inherent cost and exposure may be inevitable (although there is an indication of some relief for rural markets). This result, of course, would likely not encourage ACO formation.

We also urge the Agencies to raise the upper parameter of the safety zone to 40 percent. This percentage better reflects an accepted "rule of thumb" followed by many in the antitrust arena and would provide greater flexibility and efficiencies to develop integrated and coordinated care models.

II. The Policy's Market Analysis Does Not Create a Level Playing Field for All Provider Models

The FAH is concerned that the approach taken to PSA market analysis will have a significant tendency to create an unwarranted advantage for ACOs which are based on physician employment models, as opposed to those ACOs which seek to pursue integration of, and coordination with, an independent medical staff. Because the PSA analysis is based on the addition of PSA shares from two or more independent practitioners, a group that employs all the physicians (through acquisition or accretion by employment over time) is much less likely to face the burdens and time constraints of mandated antitrust scrutiny. This is likely to be the case, notwithstanding the dominant provider limitation set forth in the Policy.

III. The Policy Should Provide More Guidance on How the Rule-of-Reason Will Be Applied

We appreciate and support the Agencies' proposal to evaluate MSSP ACOs under the rule-of-reason, which provides an appropriate balancing test to analyze their competitive implications. However, the final Policy should contain more detail to explain how the rule-of-reason will be applied. While there are overarching antitrust policies that provide a general framework for the area, the health care field has long sought more information about how these policies will be applied in a clinical integration context. The existing FTC advisory opinions on the topic provide some guidance, but the implementation of the MSSP ACO program affords a grand opportunity for the Agencies to issue more specific guidance to better define the parameters of acceptable integrated and coordinated care arrangements.

The Policy indicates it will extend rule-of-reason treatment to ACO activities, in the commercial market, if the entity uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the MSSP. The structure and processes that must be the same or similar should be clarified. Many of these mandated ACO processes and structural elements have little to do either with market power or clinical integration. Examples are many, and include requirements with respect to public disclosure of savings and related financial information (which may be prevented by contract) and the use of the same quality metrics.

The Policy indicates that rule-of-reason treatment will apply to the ACO for the duration of its participation in the MSSP. This, of course, creates a challenge if the MSSP contract is terminated, or

expires and is not renewed. If the ACO entity continues to operate in materially the same integrative manner with respect to care delivery and quality oriented processes (for example, in commercial markets outside of the MSSP), there would seem to be little reason to withdraw rule-of-reason treatment. Analogous issues arise with respect to activities leading up to ACO creation.

IV. The Policy Should Provide Greater Flexibility on Exclusivity

The concerns about market power have led to an approach with respect to exclusivity which is overly conservative, and may retard the growth of ACOs, rather than promote them in a manner which actually supports evidence-based, integrative medical delivery systems. Specifically, to fall within a safety zone, any participating hospital and ambulatory surgical centers must be non-exclusive. Yet it is this exclusivity which may significantly enhance the ability to provide integrated care delivery. As the FTC has stated in addressing clinical integration in other contexts, "ancillarity" in the form of in-network referral requirements and arrangements similar to closed panels may make the positive aspects of integration more effective and potentially efficiency enhancing. (*See* Tristate Advisory Opinion.) Moreover, in many areas, hospitals may be significant catalysts to ACO formation, providing capital, infrastructure, and systems support which otherwise simply would not be available. **Requiring a hospital committed to an ACO in such a significant fashion to be a participant in other ACOs in the area is an unreasonable mandate where a clear market power result would not exist.**

Finally, additional clarification is needed with respect to the meaning of a provider being "exclusive." Does it mean just that there is a contractual requirement for exclusivity, or does it also include instances where a hospital or other provider elects on its own to participate in only one ACO? If the result of the effort is that there will not be many entities choosing to form ACOs and participate in the MSSP, a hospital may have little choice but to participate in only one ACO.

V. Conduct to be Avoided by an ACO Should Be Revisited

The Policy lists five types of conduct to be avoided by an ACO which, in turn, will "reduce significantly" the likelihood of an antitrust investigation. Several of these elements need further consideration, particularly where market power is not an issue. For example, conduct which consists of preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers apparently is to be avoided. To adopt such a blanket approach would seem counter to programs designed to promote differentiation based on cost, quality, efficiency, or simply the agreement to participate at a high level in integrative programs, reviews and service line quality improvement processes.

Similarly, a restriction on the ability to contract with specialists (and others) on an exclusive basis may lead to a range of issues, including inadequate case flow to maintain high level specialty skills, inefficiency and inconsistency in patient transfer and transition processes, and a decreased desire to participate in an ACO altogether given the overall level of commitment (and potential investment) required to achieve any degree of success in the form of shared savings.

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There is general recognition that the process of creating an ACO as envisioned by the CMS Proposed Rule is arduous and one that relatively few, if any, providers will even attempt. For those that do pursue such an approach, it is important to offer the type of encouragement that the Agencies

recognize is important. At the same time, the Agencies should recognize that there are a multitude of other efforts to pursue the benefits of clinical integration, which also would benefit from certainty and should not be adversely affected from a competitive standpoint by the Policy. Accordingly, the FAH urges that the Agencies continue to work both with CMS and with the health care community to ascertain how to move the benefits of clinical integration forward not just for ACOs, but through the creation of a Policy that addresses both ACOs and other health care integration and coordination efforts in a positive way.

The FAH appreciates the opportunity to comment on the proposed Policy. If you have any questions about our comments or need further information, please contact me or Jeff Micklos of my staff at (202) 624-1500.

Sincerely,