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Transforming
Healthcare
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May 31, 2011

VIA ELECTRONIC SUBMISSION

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

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

Re: Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program, Matter V100017

Dear Assistant Attorney General Varney and Commissioner Leibowitz:

On behalf of the Premier healthcare alliance serving more than 2,500 leading hospitals and health systems and 70,000-plus other healthcare sites, we would like to provide comments on the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program issued jointly by the Federal Trade Commission (FTC) and Department of Justice (DOJ) on March 31, 2011 (Policy Statement). Premier, a 2006 Malcolm Baldrige National Quality Award recipient, maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Our comments primarily reflect the concerns of our owner hospitals and health systems which, as service providers, have a keen interest in the effective operation of ACOs. This is particularly true of the nearly 90 health systems participating in our Accountable Care Collaboratives, launched in May 2010.

BACKGROUND

The Premier healthcare alliance believes that, as a nation, we all must work to rein in spiraling U.S. healthcare costs, expand access, promote wellness and improve the consistency of quality outcomes. We know we need to move from a disjointed, siloed "system" of delivery to one that is better coordinated and aligned to provide real *value* to

patients, providers and payers alike. But, this requires a new vision, new culture, and new practices—none of which are easy to achieve in healthcare.

While still evolving, the concept of ACOs is gaining ground and represents a way to overcome today's challenges without rationing care or dramatically increasing taxes. ACOs are designed to closely connect groups of providers who are willing and able to take responsibility for improving the overall health status, care efficiency and experience for a defined population. Thus ACOs can overcome the fragmentation and volume orientation of our existing fee-for-service system to more appropriately incent health and wellness, rather than treatment for illnesses. Achieving these incentives will "bend the cost curve" and revolutionize how care is paid for, provided and received.

Nearly 90 of our member healthcare systems have already started this journey with Premier to accelerate the development of innovative models for delivering care in the private sector, with the goal of participating in the Medicare Shared Savings Program (MSSP) as soon as it is operational. Premier applauds the FTC and DOJ's efforts in developing a workable framework for review of ACOs under the antitrust laws and offers the following comments concerning the Policy Statement.

POLICY STATEMENT COMMENTS

1. Greater Flexibility Needed to Demonstrate the Absence of Monopoly Power

Market share information is meaningful only if it is an accurate predictor of a competitor's ability to exercise market or monopoly power. Primary Service Area (PSA) share information based only on services provided to Medicare beneficiaries does not provide an accurate picture of the true competitive landscape. We applaud the FTC and DOJ's efforts to choose data that will be widely available. However, since the FTC and DOJ have put the burden on ACO applicants to demonstrate that their ACO will not be anticompetitive, those applicants should be able to present any form of reliable data to satisfy that burden. The methodology for determining would-be ACO participants' share of a PSA, which is ambiguous, costly, and even though it implies a geography-based approach, it is based on a technique not generally used by geographic information system (GIS) professionals, especially in relation to the zip code contiguity requirement. It would require a significant investment of hospitals' resources to perform an antitrust assessment before making an application to the MSSP. Though antitrust law is always an appropriate concern for healthcare providers, the Policy Statement as proposed would restrict rather than promote entry in the ACO arena due to the laborious and uncertain PSA share calculation process. ACOs should not be confined to one metric for calculating PSA shares, particularly when that metric is not one that healthcare providers or the FTC and DOJ have used traditionally as a proxy for market power.

Recommendation: Where other sources of data are available, such as the number of physicians in a given specialty practicing within the same PSA, the FTC and DOJ should permit ACO applicants to calculate shares of common services based on those other sources of data and commonly-accepted methodologies.

2. Clarification Requested on Market Share Calculation

For purposes of calculating the ACO applicant's PSA, it is not clear whether the ACO applicant includes all patients – irrespective of payor source – or only Medicare patients, since the ACO applicant then calculates its respective share based on data for services rendered to Medicare beneficiaries only. In addition, it is not clear whether an ACO applicant counts unique patient visits only – or the overall number of office visits – in its calculation.

Recommendation: Please clarify whether the denominator is (i) all patients – irrespective of payor source – or (ii) Medicare patients only. In addition, please clarify that an ACO applicant should count unique patient visits only in its calculation of its patients.

3. FTC/DOJ Should Extend Application of the Rule of Reason

The Policy Statement provides that the FTC and DOJ will apply the rule of reason to an ACO only for the duration of its participation in the MSSP. Therefore, an ACO that ceases to participate in the MSSP but continues to offer and provide services to commercial payors using essentially the same structure would no longer have certainty in rule of reason treatment. Similarly, an ACO that offers and provides services only in the commercially-insured market, but which is structured substantially in a manner that would qualify for participation in the MSSP, also would not have the certainty of rule of reason treatment. Finally, the Policy Statement will only apply to ACOs formed after March 23, 2010, so those networks formed before that date also would not have the certainty of rule of reason treatment.

Recommendation: The FTC and DOJ should apply rule of reason analysis to: (a) any CMS-approved ACO following the expiration of its contract with CMS, unless the ACO substantially alters its structure; (b) any CMS-approved ACO that was formed prior to March 23, 2010; and (c) any ACO participating only in commercial payor programs, that is structured in a manner substantially similar to CMS-approved ACOs.

4. Safety Zone Treatment Should Be Available to ACOs With Exclusive Hospital and ASC Participants

The Policy Statement provides that all hospitals and ambulatory surgery centers (ASCs) participating in an ACO must be non-exclusive to the ACO in order for the ACO to qualify for the proposed safety zone, irrespective of the hospital and ASC participants' PSA shares. A hospital or ASC participant that has a PSA share of 30 percent or less would be unlikely to be able to exercise market or monopoly power even if that participant is exclusive to the ACO. Premier does not understand why the FTC and DOJ would create a different antitrust standard for hospitals and ASCs as compared to other ACO providers. ACOs that otherwise meet the requirements of the safety zone, but which desire to have their hospital and ASC participants participate on an exclusive basis, should be able to have the certainty of safety zone treatment.

Recommendation: Safety zone treatment should be available to ACOs with exclusive hospital and ASC participants, as long as those ACOs do not have more than a 30 percent market share of any common service within the same PSA.

5. Policy Statement Should Require FTC/DOJ to Explain Basis for Challenge Letter

The Policy Statement does not require the reviewing agency to explain to an ACO applicant the basis for the reviewing agency's conclusion that it is likely to challenge or recommend challenging the ACO under the antitrust laws. As a result, ACOs that receive adverse determination letters not only would be prevented from participating in the MSSP, but also would have no relevant information from the reviewing agency to enable them to restructure their provider composition or take other actions that could alleviate the reviewing agency's concerns.

Recommendation: The Policy Statement should require the reviewing agency to explain to an ACO applicant the basis for the reviewing agency's conclusion that it is likely to challenge or recommend challenging the ACO under the antitrust laws.

6. Policy Statement Should Include Appeal Rights

The Policy Statement is silent regarding any appeal rights or process for an ACO applicant that receives an adverse determination letter. Therefore, ACOs receiving adverse determination letters would be foreclosed from participating in the MSSP unless they successfully pursue a challenge of that determination in court, which is an expensive and time-consuming process.

Recommendation: The Policy Statement should specify that an ACO applicant that receives an adverse determination letter has a right of appeal and should specify the appeal process. This should include the right to make changes identified by the reviewing agency in its determination letter without having to re-start the entire review process.

7. FTC/DOJ Should Expand Rural Provider Exception to Two Physicians Per County

Premier applauds the FTC and DOJ for acknowledging the unique challenges faced by rural ACOs and believes that the rural exception to the proposed safety zone will greatly assist providers seeking to establish ACOs in rural areas. A rural provider's PSA will often cover a very large geographic area, and we believe that it makes sense that an ACO be permitted to include providers of a given physician specialty in each rural county even if that will result in the ACO having a greater than 30 percent market share of a common service within a given PSA. However, limiting the rural provider exception to one such physician per county places an unfair burden on that rural provider to cover all of the ACO's patients in the county 100 percent of the time, irrespective of illness, vacation, continuing medical education seminars or other absences. Furthermore, in those situations, it will often be impractical to expect patients to travel to another county to see a covering ACO provider.

Recommendation: To relieve the burden of covering ACO patients in rural counties, the FTC and DOJ should expand the rural provider exception to allow inclusion of two individual physicians per specialty in each rural county.

8. FTC/DOJ Should Clarify Non-Application of the Policy Statement to Vertically-Integrated ACOs

The Policy Statement states that it applies to collaborations among competing providers and provider groups. Collaborations are defined as a set of agreements, other than merger agreements, among otherwise independent entities to engage in joint economic activity, and the resulting economic activity. Presumably, therefore, the Policy Statement does not apply to any ACO whose provider participants are all viewed under the antitrust laws as a single economic entity, such as a vertically-integrated health system.

Recommendation: The FTC and DOJ should clarify that the Policy Statement does not apply to any ACO whose provider participants are all viewed under the antitrust laws as a single economic entity, such as a vertically-integrated health system.

9. FTC/DOJ Should Establish Definition or Guidelines for When an ACO's Provider Composition Might Change Significantly

The Policy Statement provides that the FTC and DOJ will apply safety zone treatment to an ACO for the duration of its agreement with CMS, unless the ACO's provider composition changes significantly. The Policy Statement does not establish a definition or provide any guidance regarding the circumstances under which the agencies may conclude that an ACO's provider composition has changed significantly. As a result, ACOs whose provider composition may change over time – which is likely the majority of ACOs – do not have certainty regarding when those changes may result in the loss of safety zone treatment.

Recommendation: The FTC and DOJ should establish a definition or provide guidance regarding the circumstances under which the agencies will conclude that an ACO's provider composition has changed significantly.

10. FTC/DOJ Should Elaborate On Review Criteria For ACOs Exceeding the 50 Percent PSA Share Threshold

The Policy Statement states that the 50 percent PSA threshold triggering mandatory agency review provides a valuable indication of the potential for an ACO to harm competition, but that the agencies will consider (a) any information or alternative data suggesting that the PSA shares may not reflect the ACO's likely market power and (b) any substantial procompetitive justification for why the ACO needs a large share of the market in order to provide high-quality, cost-effective care to Medicare beneficiaries. However, the FTC and DOJ do not explain what other types of information they consider relevant to rule of reason analysis in this context. The calculation of market shares is only the beginning, and not the end, of the relevant analysis. The FTC and DOJ must consider the competitive implications of

the formation and operation of an ACO in the particular marketplace in which the ACO will compete. The lack of a review framework in the Policy Statement, however, raises questions about whether the FTC and DOJ intend to look beyond PSA shares.

Recommendation: The FTC and DOJ should explain what other types of information they consider relevant to a rule of reason analysis in the ACO context, as well as the specific rule of reason analysis that they will apply to ACOs.

11. Information ACOs Must Submit For Mandatory Agency Review Should Be Limited to Information on Common Services Exceeding 50 percent PSA Share

ACOs that are required to undergo mandatory agency review must submit certain enumerated documentation and information to the reviewing agency. However, the documentation and information that the ACO is required to submit is not limited only to information pertaining to those common services for which the ACO's PSA share exceeds 50 percent. As a result, an ACO required to undergo mandatory review will be required to obtain, prepare, and produce more information than may be necessary for the underlying review and analysis. This is expensive and burdensome for the ACO and places undue burden on the reviewing agency as well.

Recommendation: ACOs that are subject to mandatory agency review should only be required to submit information pertaining to those common services for which the ACO's PSA share exceeds 50 percent and any closely related common services (e.g., cardiology and cardiovascular surgery).

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We thank you for the opportunity to submit these comments on the Policy Statement.

Sincerely,

Blair Childs
Senior Vice President, Public Affairs