Hospital Sisters
HEALTH SYSTEM

May 26, 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:

Hospital Sisters Health System (HSHS) is pleased to submit 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).

HSHS is an integrated health care delivery system that comprises 13 hospitals, multiple physician groups, clinics, a school of nursing, and other services, in Illinois and Wisconsin. As our name implies, we are a healing ministry guided by the historic mission of the Hospital Sisters of St. Francis. We provide health care to all, with a special emphasis on the poor and underserved. We are also a nationally recognized champion of evidence-based medicine and are currently developing coordinated delivery systems focused on both patient-centered and high-value care.

HSHS agrees that improvements in care integration are essential to achieving the goals of the Triple Aim—enhancing patient experience, improving quality, and lowering healthcare costs. Since

February 2008, HSHS has pursued a multi-pronged Care Integration Strategy that includes:

- Implementing clinical informatics capabilities system-wide and creating a clinical integration network with independent physicians.

- Advancing the Patient-Centered Medical Home (PCMH) -- considered by many experts to be a foundational element for ACOs -- in three rural sites and at Prevea Health, our Wisconsin-based medical group partner.

- Participating through Prevea Health in the NCQA pilot testing of ACO standards.

- Working with the Geisinger Health System and Bon Secours Virginia in a "Care Transformation Collaborative" to develop and test the replicability of care coordination models for selected cardiac conditions and for patients with multiple chronic conditions.

HSHS has clearly demonstrated a strong commitment to the delivery of high value health care and acknowledges the FTC and DOJ's efforts in developing a workable framework for review of ACOs under the antitrust laws. Below, we offer detailed comments on, specific recommendations for, and requests for additional clarification of the Policy Statement.

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

Concern: Market share information is meaningful only if it is an accurate predictor of a competitor's ability to exercise market or monopoly power. PSA share information based on services provided to Medicare beneficiaries only in primary service areas (PSAs) does not meet that objective, particularly for commercial patients and the total population. While we applaud the FTC and DOJ's efforts to choose data that will be widely-available, because the FTC and DOJ have put the burden on ACO applicants to demonstrate that their ACO will not be anticompetitive, ACO applicants should be able to present any form of reliable data to satisfy that burden. ACO applicants should not be confined to one metric for calculating PSA shares, particularly when that metric is not one that health care 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 practicing in a 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

Concern: 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.

Recommendation: Please clarify whether the denominator is (i) all patients – irrespective of payor source – or (ii) Medicare patients only.

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

Concern: 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 Medicare Shared Savings Program. Therefore, an ACO that ceases to participate in the Medicare Shared Savings Program but continues to offer and provide services using essentially the same program to commercial insurers and their members no longer has the certainty of rule of reason treatment. Similarly, an ACO that offers and provides services only in the commercially-insured market that is substantially similar to one that would qualify for participation in the Medicare Shared Savings Program also does not have the certainty of rule of reason treatment. Finally, the Policy Statement provides that it applies to ACOs formed after March 23, 2010, so those formed before this date also do not have the certainty of rule of reason treatment.

Recommendation: The FTC and DOJ apply rule of reason analysis to any ACO that would meet all of CMS' criteria for participation in the Medicare Shared Savings Program if it were participating in the Medicare Shared Savings Program – irrespective of when the ACO was formed or whether it participates in the Medicare Shared Savings Program.

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

Concern: The Policy Statement provides that all hospitals participating in an ACO must be non-exclusive to the ACO in order for the ACO to qualify for the safety zone, irrespective of the hospital participants' PSA shares. A hospital participant that has a PSA share of 30 percent or less is unlikely to be able to exercise market or monopoly power even if that hospital participant is exclusive to the ACO, and ACOs desiring to have their hospital participants participate on an exclusive basis that otherwise meet the requirements of the safety zone should be able to have the certainty of safety zone treatment.

Recommendation: Safety zone treatment should be available to ACOs with exclusive hospital participants where the ACO otherwise meets the requirements of the safety zone.

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

Concern: The Policy Statement does not require the reviewing agency to explain to an ACO applicant the basis for the reviewing agency's conclusion in a letter stating that it is likely to challenge or recommend challenging the ACO if it proceeds. As a result, ACOs that receive adverse determination letters not only would be prevented from participating in the Medicare Shared Savings Program, but they also would have no relevant information from the reviewing agency to enable them to restructure their composition or take other action 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 in a letter stating that it is likely to challenge or recommend challenging the ACO if it proceeds.

6. Policy Statement Should Include Appeal Rights and Process for ACOs Receiving Challenge Letters

Concern: The Policy Statement is silent regarding any appeal rights or process for an ACO applicant that receives a letter from the reviewing agency stating that it is likely to

challenge or recommend challenging the ACO if it proceeds. Therefore, ACOs receiving adverse determination letters would be foreclosed from participating in the Medicare Shared Savings Program 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 a letter from the reviewing agency stating that it is likely to challenge or recommend challenging the ACO if it proceeds has a right of appeal and should specify the appeal process.

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

Concern: Limiting the rural provider exception to one physician per county places an unfair burden on that rural provider to cover all patients in the ACO 100 percent of the time irrespective of illness, vacation, continuing medical education seminars or other absences.

Recommendation: To relieve the burden to cover ACO beneficiaries 100 percent of the time, the FTC/DOJ should expand the rural provider exception to allow inclusion of two individual physicians per rural county.

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

Concern: The Policy Statement states that it applies to collaborations among other competing providers and provider groups. Collaborations are defined as a set of agreements, other than merger agreements, among otherwise independent entities jointly to engage in 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/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 a ACO's Provider Composition Might Change Significantly

Concern: The Policy Statement provides that the FTC/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 FTC/DOJ 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/DOJ should establish a definition or provide guidance regarding the circumstances under which the FTC/DOJ may conclude that an ACO's provider composition has changed significantly (e.g., when the ACO's market share moves from below to above 50 percent for a physician specialty).

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

Concern: The Policy Statement provides that the 50 percent share threshold for mandatory review provides a valuable indication of the potential for competitive harm from ACOs with a high PSA share but that the agencies will consider any information or alternative data suggesting that the PSA shares may not reflect the ACO's likely market power, and will also consider any substantial procompetitive justification for why the ACO needs that proposed share to provide high-quality, cost-effective care to Medicare beneficiaries. However, the FTC/DOJ do not explain what other types of information they consider relevant to rule of reason analysis. The calculation of market shares is only the beginning, and not the end, of the relevant analysis. The FTC/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 suggests that the FTC/DOJ does not intend to look beyond PSA shares.

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

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

Concern: ACOs 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.

Recommendation: Information ACOs must submit for mandatory agency review should be limited to information pertaining only 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 provide feedback on this important program.

Sincerely,

Larry Schumacher
Chief Operating Officer

Frank Mikell, M.D.
Chief Physician Executive

cc: William H. Roach, Jr., Esq.
Ashley M. Fischer, Esq.