MERCY
SISTERS OF MERCY
HEALTH SYSTEM

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: 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 Mercy Health, we are providing comments to your respective agencies on the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (Statement). We very much appreciate the antitrust agencies' recognition of the importance of integrated health organizations, like ACOs, and the historic effort to work cooperatively with other federal agencies to craft a legal and regulatory framework for the Medicare Shared Savings Program (ACO Program).

We respectfully submit that the proposed Statement, in its current form, introduces unnecessary uncertainty and costs to the formation and maintenance of ACOs. Additionally, in certain instances it creates barriers to participation at all. These results will undermine the purpose of the ACO Program of incentivizing otherwise independent health care providers and suppliers to work together to manage and coordinate care.

The use of a new calculation methodology for market share measurement is one of the elements of the Statement that adds significantly to the complexity of the determination of eligibility for ACO Program status but does not necessarily protect against antitrust risk. Under the proposed Statement a single common service above 50% among hundreds of ACO providers each of which has multiple services, would elevate an immaterial overlap to full blown agency review. The mere existence of such a common service is not indicative of an ability to raise prices in the common service by

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the ACO. And the testing process to prevent such overlap is complex, burdensome in its resource-intensity. As a result, this approach creates a barrier to an otherwise precompetitive ACO absent a bona fide antitrust concern.

The Statement also creates barriers to ACO participation by appearing to designate activities allowed under traditional antitrust analysis as being potentially problematic in an ACO setting. For example, stating that "an ACO may not require a purchaser to contract with all the hospitals in the same network as the hospital that belongs to the ACO" does not take into account that outside the ACO program, such a negotiation is permissible if the hospitals fall within the Copperweld doctrine. The mere fact of participation in the ACO program should not diminish existing protections.

An example of how the Statement as proposed is not in concert with the ACO Program is that the Rural Exception only allows for the inclusion of "one physician per specialty." No allowance is made for the likelihood that rural practitioners may work in a group practice. It would not be practical to expect that only a single practitioner from a group would participate in an ACO. In light of the fact that ACO participants are determined by their tax identification number rather than by individual practitioners it is inconsistent for an antitrust exception to be measured otherwise.

The Safety Zones as proposed are also problematic. For example, the Safety Zone restrictions against exclusivity for certain ACO participants are inconsistent with the ACO program expectations about the level of integration among the parties needed to be a successful. ACO participants are required to exercise significant governance control, to actively participate in and be able to influence or direct the clinical practice of the ACO providers, and to commit to a meaningful financial or time/effort investment. It is unrealistic to expect that ACO participants would be able to meet that standard with respect to multiple ACOs even if they desired to (which is unlikely). Further, in order to be successful under the ACO Program requirements, an integrated electronic health record (EHR) will be essential. The capital investment and ongoing resource requirements of an EHR are significant and unlikely to be replicated in order for a provider to participate in multiple ACOs. As a result, the exclusivity restrictions in the Safety Zone should be eliminated as they create uncertainty in the antitrust treatment of those ACOs which are structured to operate in accordance with the express intention of the ACO Program.

By its nature, the ACO Program will require that ACOs behave in a clinically integrated fashion and reduce cost to the ultimate consumer. Many of the concerns raised by the antitrust agencies are misplaced in the context of the ACO Program because the primary focus of ACOs will be on Medicare beneficiaries for whom there is no price competition, as the terms, conditions and reimbursement are dictated solely by a federal agency. Further, the technical application of the Statement seems to elevate issues that would not traditionally rise to the level of antitrust concern in a way that does not serve either the goals of the ACO program or the purpose of the antitrust laws. We believe that the goals of the ACO Program should be promoted even by ACOs that provide care to a

significant share of Medicare beneficiaries in a given market rather than have such providers not included in the ACO Program.

As a result of all of the above, as an alternative to the mandatory or optional review process based on complex calculations of each participating provider's share of each service as proposed in the Statement, we recommend that the antitrust agencies apply Rule of Reason to all entities which are accepted into the ACO Program irrespective of market share unless there is clear evidence of anticompetitive behavior and to eliminate the requirement of prior antitrust agency review. To do otherwise, (i) imposes more restrictive antitrust limitations on ACO participation than those under traditional antitrust analysis where this kind of clinical integration would already receive Rule of Reason treatment and (ii) impedes the ability of the ACO Program to be successful by presenting barriers to inclusion of otherwise available ACO participants. Impact on pricing during the Program could be measured so that any collateral effects could be managed going forward based on objective data. If a broad waiver as requested above is not granted, at a minimum the threshold for requiring full agency review should be revised to impact only those ACOs which have significant overlaps of a material nature. This approach will permit an ACO to know in advance how to structure its arrangements without the requirement for antitrust review even if primary service area market share is greater than 50% in any single Medicare specialty code, major diagnostic category or outpatient category. The guidelines should also specifically address how competitively price sensitive and other data among ACO Participants can be shared without implicating activities outside the ACO.

The Medicare ACO Program provides an opportunity for the antitrust agencies to issue guidance on how the agencies will analyze ACOs, and similarly clinically integrated organizations under the rule of reason where the benefits of better care for individuals, better health for populations and lower growth in healthcare costs are balanced against the potential harm to consumers from the clinical integration of otherwise independent providers. We believe this will be best done through a broad waiver that allows all healthcare providers the opportunity to fully participate in the ACO Program without regard to market share and without the requirement for prior review.

We sincerely appreciate the agencies' willingness to consider our comment and we look forward to working with the agencies to make the ACO Program a success.

Sincerely,

Lynn Britton
President and Chief Executive Officer