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

WHY THIS GUIDANCE SHOULD BE CHANGED

The primary question posed by the agencies to prospective ACO applicants in the Statement is: "[w]hether and, if so, why, the guidance in the proposed policy statement should be changed." The simple answer is "yes;" in order for the Medicare ACO program to achieve its ambitious goal of helping to transform the way in which health is paid for and delivered to benefit patients and communities, the antitrust agencies must make changes in their approach. In its current form, the Statement will serve as a barrier to participation in the

Medicare ACO program and will not provide the guidance needed to spur adoption of and continued innovation in clinical integration beyond the Medicare program.

We urge your agencies to revise the Statement, and instead provide user-friendly guidance on how the agencies will analyze, under the rule-of-reason, clinically integrated organizations, that are or are similar to Medicare ACOs, to avoid or minimize antitrust risk. Guidance should not be a prerequisite for participation in the Medicare ACO program; rather, the agencies should continue to respond to concerns as they arise in the marketplace. The agencies should also provide for a streamlined process for clinically integrated organizations to receive more specific advice that works in sync with the Centers for Medicare & Medicaid Services' ("CMS") application process for the Medicare Shared Savings Program.

THE STATEMENT SHOULD PROVIDE GUIDANCE ON HOW THE RULE OF REASON ANALYSIS WOULD BE APPLIED.

One of the most useful features of the Statement was assurance that Medicare ACOs would be reviewed by the antitrust agencies under the rule-of-reason, which balances pro-competitive potential against anticompetitive risk. Guidance from the agencies on how that analysis would be applied would assist hospitals and other providers in forming and operating such clinically integrated organizations.

The hospital field has long sought guidance from the antitrust agencies on clinical integration, similar to that in the Statements of Antitrust Enforcement in Health Care. It was the 1996 Statements that first broadened the concept of legitimate provider integration to include clinical integration. Since then, the agencies have declined to provide guidance in a similar manner, despite calls by members of Congress, the hospital field and others for such guidance. The Medicare ACO program provides an opportunity for the antitrust agencies to issue such guidance focused on how the agencies will analyze ACOs, and similarly clinically integrated organizations, under the rule-of-reason.

The 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 operate essentially the same program in the commercial arena no longer has the certainty of rule of reason treatment. Similarly, an ACO that operates a program only in the commercial setting 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 Statement provides that it applies to ACOs formed after March 23, 2010, so those formed prior to this date do not have the certainty of rule of reason treatment. The agencies should extend rule of reason treatment 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.

THE PROPOSED FORMULAS SHOULD BE ABANDONED

The Statement proposes a new formula to determine the shares of each prospective ACO participant in its "Primary Service Area" (PSA). Shares must be calculated for *each* common service to be provided by *each* participating hospital and doctor (or group of doctors) within *each* provider's PSA. PSA is defined as the lowest number of contiguous zip codes from which the provider draws at least 75 percent of its patients. Among the concerns with this new formula are that it is untested, certain to be burdensome and costly, certain to pose great difficulties when non-Medicare services are to be included in the ACO and could raise issues for hospitals that undertake the PSA analysis on behalf of physicians under the fraud and abuse laws if no waiver is provided:

- Calculating PSA shares on the basis of Medicare fee-for-service data is likely to be unreliable and will be practically unavailable for any service or medical specialty that does not routinely provide services to Medicare patients, such as obstetrics, pediatrics, burn units and HIV services, for example. The data will also overstate the shares of providers who care for large numbers of Medicare patients and understate the shares of those who restrict their practices to commercially-insured patients. Even where Medicare fee-for-service data might be available, it will be extremely difficult for physicians to pull zip code data and match it with billing records to obtain the services provided.

- Calculating PSA shares on the basis of contiguous zip codes likely will be burdensome and costly and require substantial judgment calls.

- The Stark law may be implicated if a hospital provides a "benefit" for physicians participating in an ACO by organizing and paying for the costly analysis required to determine the physicians' PSA shares. There is no indication in the notice issued by CMS and the Office of Inspector General on waivers in connection with the Medicare ACO program or that a waiver for such activities and expenses is being considered for this form of benefit.

MANDATORY REVIEW SHOULD NOT BE REQUIRED

Under the proposed Statement, any prospective Medicare ACO applicant that received a PSA score of 50 percent or above for any service or specialty is subject to *mandatory* review by one of the antitrust agencies. This is true, even if the score is for a non-Medicare service, such as pediatrics, and even if the ACO applicant's PSA share is well below 50 percent for the vast majority of services provided.

Mandatory review is not confined to the specific service(s) over 50 percent, but will subject the entire Medicare ACO applicant to antitrust scrutiny. Practically, this means that a prospective applicant with even a single PSA above 50 percent would need to: (1) submit a large number of documents (that do not overlap with those required by other agencies); and (2) obtain a time-consuming and expensive antitrust analysis from an antitrust practitioner, to be prepared to defend its ACO application before one of the agencies.

Further, this approach inappropriately delegates to the antitrust agencies the authority to determine which prospective ACO will be permitted to apply for the Medicare ACO program based on concerns about whether the ACO could impact price competition in the private sector. This concern seems particularly misplaced because the application at issue would be to participate in the Medicare ACO program, a program in which there is no price competition, as the terms, conditions and reimbursement provided are dictated solely by a federal agency.

The antitrust agencies could make a positive contribution by developing a truly streamlined process (90 days or less) that *allows* prospective ACO applicants to obtain antitrust guidance at the same time CMS is reviewing the application. Such a process would also aid other clinically integrated organizations.

CONCERNS ABOUT THE SAFETY ZONE

There are concerns about the Safety Zone that should be addressed:

- Although it is helpful to create a safety zone within which the agencies will not challenge ACOs, the Statement does not provide direct relief from private rights of action under the antitrust laws even where the safety zone is met. At a minimum, the Statement should confirm that fitting within the safety zone provides an affirmative defense against private actions alleging breach of the antitrust laws.

- The safety zone of 30 percent or less is too low and should be increased to at least 35 percent.

- Qualifying for the safety zone should not require that participants contract or even be able to contract with other ACOs. Exclusivity will likely be an important tool to ensure that a Medicare ACO is able to meet the quality reporting and health information technology meaningful use requirements, among others, in the CMS rule. A hospital participant that has a PSA share of 30 or 35 percent or less is unlikely to be able to exercise antitrust 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.

- The indicia of "clinical integration" included in the CMS rule and relied on by the antitrust agencies is overly prescriptive. This includes, for example, a "leadership and management structure" that anticipates a formal governing body where "ACO participants hold at least 75 percent control." The antitrust agencies instead should specify which criteria are related to antitrust issues and applicable to clinically integrated health care organizations.

- The rural exception is too narrow. Limiting the rural provider exception to one physician per specialty per county places an unfair burden on that rural provider to cover all of an ACO's patients for 100 percent of the time irrespective of illness, vacation, continuing medical education seminars or other absences. Having a larger share of providers where necessary should be allowed under the exception if the providers are nonexclusive (available to work with others).

We appreciate the work and collaboration among the agencies that went into the Statement; however, in its current form, it will be an unfortunate barrier to Medicare ACO formation and operation. We hope the antitrust agencies will take this opportunity to substitute improved guidance for the Statement as well as a streamlined and voluntary process to obtain advice from the agencies. We look forward to working with the agencies to make the Medicare ACO program a success and to lay a stronger foundation for other clinically integrated arrangements to flourish.

Sincerely,

Rick L. Grossman,
Vice President and Associate General Counsel