



Arizona Hospital and Healthcare Association

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 our 104 member hospitals and healthcare organizations, AzHHA is 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 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 to the first question is "yes." As to the second, for the Medicare ACO program to achieve its ambitious goal of helping transform the way in which health care is paid for and delivered to benefit patients and communities, the antitrust agencies must make fundamental changes in their approach. In its current form, the Statement will serve as a significant and unnecessary 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 both in the Medicare program and beyond.

We urge your agencies to substantially revise the Statement so that it provides straightforward and user-friendly guidance on how the agencies will analyze, under the rule-of-reason, clinically integrated organizations generally, not just those organizations that are or are like Medicare ACOs. Furthermore, as set forth more fully below, guidance should not be a prerequisite for participation in the Medicare ACO program, instead 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.

THE STATEMENT LACKS MEANINGFUL GUIDANCE

One of the most useful features of the Statement is its assurance that Medicare ACOs would be reviewed by the antitrust agencies under the rule-of-reason, which balances pro-competitive potential against anti-competitive risk. Guidance from the agencies on how that analysis will be applied will 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 repeatedly declined to provide additional guidance in a similar manner, despite repeated calls by members of Congress, hospital industry representatives, and others. The development of the Medicare ACO program provides an opportunity for the antitrust agencies to issue such guidance focused on how the agencies will analyze ACOs and similar clinically integrated organizations under the rule-of-reason.

THE PROPOSED FORMULAS SHOULD BE ABANDONED

The Statement proposes a new, untested, and highly problematic formula to determine the shares of each prospective ACO participant in each participant's "Primary Service Area" (PSA). Shares must be calculated for *each* common service to be provided by *each* participating hospital, *each* outpatient surgery center, and *each* doctor (or group of doctors) within *each* provider's PSA. A PSA is defined as the lowest number of contiguous zip codes from which the provider draws at least 75 percent of its patients, an

analysis that would need to be made for each common service within the ACO.¹ Among the serious concerns with this new formula are that it is untested, certain to be extremely burdensome and costly, certain to pose great difficulties when non-Medicare services are to be provided by 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, thus increasing administrative costs and introducing uncertainty into ostensibly objective calculations.
- The Stark law prohibits a physician from referring patients to an entity that provides certain health care services if the physician has a financial relationship with the entity, unless an exception to the law is met. The entity is also prohibited for billing the Medicare program for the referral. The Stark law could therefore be implicated if the organization and payment for the costly analysis required to determine physician PSA shares is considered to create a financial relationship between an ACO-organizing hospital and participating physicians. There is no indication in the CMS and Office of Inspector General notice on waiver designs in connection with the Medicare ACO program that they are considering waiving the Stark law for such activities and expenses.

¹ We note that, in contrast to the examples in the Appendix to the Statement, functional ACOs are almost certain to have many, many common services, both for hospitals and physicians. Most hospitals, for instance, provide a full range of hospital services, and an ACO with more than one hospital will therefore have to calculate shares in “common services” for almost every service line.

MANDATORY REVIEW SHOULD NOT BE REQUIRED

Under the proposed Statement, any prospective Medicare ACO applicant with a share in *any* PSA of 50 percent or above for *any* common 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 common service in a 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.

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.

OTHER CONCERNS THAT SHOULD BE ADDRESSED

There are a number of other concerns about the Statements that should be addressed:

- The safety zone of 30 percent or less is too low and should be increased to at least 35 percent (making it parallel with the benchmark used for joint-purchasing arrangements). In addition, 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. The promise of a safety zone is seriously compromised if it is too low and exclusivity is not permitted.

- The indicia of “clinical integration” included in the CMS rule and relied on by the antitrust agencies is overly prescriptive and unnecessary. 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 should specify which criteria are related to antitrust issues and applicable to clinically integrated health care organizations.
- The rural exception is too narrow. Having more than one physician per specialty participating in the ACO should be allowed under the exception if the physicians 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 itself be an unnecessary and unfortunate barrier to the formation and operation of ACOs in both the Medicare and private markets. In addition, we believe that the Statement in its current form misses key opportunities to provide additional guidance to assist the health care industry achieve the clinical integration that health care policy makers are attempting to incent. We hope the antitrust agencies will take this opportunity to substitute for the Statement meaningful guidance and 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,



James F. Haynes
Senior Vice President and Chief Financial Officer