MedStar Health

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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 Accountable Care Organizations (ACOs) Participation in the Medicare Shared Savings Program, Matter V100017

Dear Assistant Attorney General Varney and Commissioner Leibowitz:

On behalf of MedStar Health, Inc., I am writing to provide the Department of Justice (DOJ) and the Federal Trade Commission (FTC) (jointly the "Agencies") with MedStar Health's perspective on the Agencies' Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (Statement).

MedStar Health is a large health care system in the mid-Atlantic region, comprised of nine hospitals, a Medicaid managed care organization, a research institute, a home health agency, and several outpatient surgery centers. MedStar Health employs over 26,000 associates serving the Maryland and District of Columbia region, and has in excess of 1,100 employed physicians and 5,600 affiliated physicians. Annually we provide 162,000 inpatient admissions, 762,000 inpatient days, 1,492,000 outpatient visits, and 215,000 home health visits.

As one of the largest health care systems in our region, we 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 develop an appropriate legal and regulatory framework to facilitate clinical integration of care.

While we are appreciative of the work and effort that went into developing the Statement, we do not believe the Statement provides the guidance necessary to allow providers to implement the spirit and intent of the provisions contained in the Affordable Care Act. Specifically:

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Fundamental Approach is Problematic

In order for the Medicare ACO program to achieve the intended objective of the federal Affordable Care Act to help transform the way in which health care is paid for and delivered, the Agencies must make fundamental changes to the approach taken in the Statement. 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 beyond the Medicare program.

We urge the Agencies to substantially revise the Statement to provide more specific, concrete, and user-friendly guidance on how the Agencies will apply the "rule-of reason" analysis in reviewing transactions which organizations must undertake to create the requisite clinical integration for participation in the Medicare Shared Savings Program. In addition, the agencies should provide for a streamlined process for clinically integrated organizations to receive more specific advice that works in conjunction with the Centers for Medicare & Medicaid Services' (CMS) ACO application process.

Meaningful Guidance Needed

One of the most useful features of the Statement is the assurance that Medicare ACOs would be reviewed by the antitrust agencies under the rule-of-reason test, which balances pro-competitive potential against anticompetitive risk. However, it is critical that the agencies provide guidance on how that analysis would actually be applied to assist hospitals and other providers in forming and operating such clinically integrated organizations.

As you know, the hospital field has long sought guidance from the antitrust agencies to allow for and foster clinical integration. The Medicare ACO program provides a unique opportunity for the antitrust agencies to issue such guidance focused on how the agencies will analyze ACOs, and other similar clinically integrated organizations, under the rule-of-reason approach.

Primary Service Area Formulas Should Be Abandoned

The Statement proposes a new, untested and highly problematic formula to determine the shares of each prospective ACO participant in its Primary Service Are (PSA). Under the Statement, 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. A PSA is defined as the lowest number of contiguous zip codes from which the provider draws at least 75 percent of its patients.

This approach, in addition to being untested and unproven, is certain to be extremely burdensome and costly. And, it will pose significant difficulties when non-Medicare services are to be included in the ACO and raise issues for hospitals that need to undertake the PSA analysis on behalf of physicians under the current fraud and abuse laws. Specific concerns include:

- Calculating PSA share 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, e.g., obstetrics, pediatrics, HIV services, etc.

- The data will 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 services provided.
- Calculating PSA shares on the basis of contiguous zip codes will be burdensome and costly and require substantial judgment calls.
- The Stark law could be implicated if a hospital "compensates" physicians by organizing and paying for the costly analysis required to determine PSA shares.

Mandatory Review Should Not Be Required

Under the proposed Statement, any prospective Medicare ACO applicant that received a PSA score of 50 percent or more 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.

Further, mandatory review is not confined to the specific service(s) over 50 percent, but will subject the entire Medicare ACO applicant to antitrust scrutiny. As a result, a prospective applicant with a single PSA above 50 percent would be required to: 1) submit potentially voluminous documentation over and above what is already required by other agencies and 2) obtain 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 whether the ACO could potentially impact price competition in the private sector. This seems particularly misplaced given the application at issue is for participation in the Medicare ACO program – a program in which there is no price competition, as the terms, conditions and reimbursement are dictated entirely by a federal agency.

The antitrust agencies could and should 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 in the development of other clinically integrated organizations.

Other Concerns That Should Be Addressed

There are a number of other concerns regarding the Statement that also should be addressed, including:

- The safety zone of 30 percent or less is too low and should be increased to at least 35 percent. And, qualifying for the safety zone should not require that a participant 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 other, 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. The antitrust agencies should specify which criteria are related to antitrust issues and applicable to clinically integrated health care organizations.

Conclusion

On behalf of MedStar Health, I want to express our sincere appreciation for the work and collaboration among agencies that went into the Statement. In its current form, however, it represents an unnecessary and unfortunate barrier to Medicare ACO formation and operation. We urge the antitrust agencies to take this opportunity to provide meaningful guidance and a streamlined and voluntary process to obtain advice from the agencies.
We look forward to working with your agencies to make the Medicare ACO program a success and to lay a strong foundation for other clinically integrated arrangements.

Sincerely,

Eric R. Wagner
Executive Vice President
MedStar Health