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May 31, 2011

The Honorable Christine Varney
Assistant Attorney General
Antitrust Division
United States Department of Justice
950 Pennsylvania Avenue, NW
Washington, D.C. 20530

The Honorable Jon Leibowitz
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, NW
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:

On behalf of Providence Health & Services (Providence), I want to thank you for the opportunity to provide our comments to your respective agencies on the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (MSSP).

Providence is a faith-based, non-profit health system that includes 28 hospitals, more than 34 non-acute facilities, physician clinics, a health plan, a liberal arts university, a high school, approximately 50,000 employees, and numerous other health, housing, and educational services in Alaska, Washington, Montana, Oregon and California.

As a health care system that provides services to patients across the continuum of care, from primary care, to acute care, to home health and hospice, we are committed to clinical excellence. We know that access to high-quality care improves the lives of families in the communities we serve. As such, we have an ongoing commitment to improving the quality and efficiency of the care that we deliver, regardless of our patients' social, economic, or health status. We firmly believe that Accountable Care Organizations (ACOs) and similar new payment and delivery

models are the appropriate and necessary vehicles for furthering these commitments to our patients.

Additionally, Providence believes that health care systems that deliver a high level of quality will ultimately be more equitable and sustainable. We understand that current prevalent reimbursement models do not support the redesign of care, and we believe that patients will receive better, more efficient care when payments are based upon care coordination, quality, health outcomes, and patient satisfaction. Therefore, Providence encourages, and is actively participating in, new payment and delivery models that continue to shift the health care system away from the fee-for-service model.

Providence very much appreciates 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. The level of coordination between FTC, DOJ and Centers for Medicare & Medicaid Services (CMS) clearly demonstrates the Administration's strong commitment to establish the ACO model.

THE PROPOSED GUIDANCE MISSES THE MARK

Despite the effort and intent to create an analytical framework that promotes the development of ACO models through the MSSP, we are concerned that the agencies have instead created one that is highly complex and will dissuade potential collaborations from participating in the program. In its current form, we are concerned that the Statement will serve as a significant and unnecessary barrier to participation in the Medicare ACO program. Moreover, we believe it 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 substantially revise the Statement, and instead provide for comment by all of those affected, user-friendly guidance on how the agencies will analyze, under the rule-of-reason, clinically integrated organizations, that are or are like Medicare ACOs, to avoid or minimize antitrust risk. 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 CMS application process.

PRIMARY SERVICE AREA (PSA) FORMULAS:

The Statement proposes a new, untested and highly problematic 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 serious concerns with this new formula are that it is untested, certain to be burdensome and

costly, certain to pose great difficulties for prospective ACOs that are collaborations of multiple, independent organizations (hospitals, physician groups and other providers) 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 requires that compensation for health care providers be fixed in advance and paid only for hours worked. The Stark law could be implicated if a hospital compensates physicians by organizing and paying for the costly analysis required to determine physician 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.

These challenges are further magnified by the prospect of a mandatory review if one service or specialty falls above a 50 percent PSA share. Given the substantial cost of compiling and assessing PSA data, a calculation error in determining PSA share could result in the ACO being required to submit to a mandatory review – even if the ACO's share is well below 50 percent in every other service or specialty.

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 practical matter, 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.

Additionally, Providence believes 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. This was not Congress' intent when the MSSP provision was adopted as part of the Affordable Care Act (ACA).

The antitrust agencies could make a positive contribution by developing a truly streamlined process (90 days or less) that provides a true "screen" 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 pursuing new delivery models through the Center for Medicare and Medicaid Innovation (CMMI) or with states or private payers.

Alternatively, Providence recommends that the agencies utilize third party reviewers for those potential applicants whose PSA share is above the "safety zone" of 30 percent that submit to a voluntary, expedited antitrust review, or conduct a blind analysis that allows the applicant to make necessary changes without jeopardizing its future participation in the MSSP. We also strongly recommend that the agencies regularly publish advisory opinions on reviews so that other potential applicants can learn from their predecessors.

OTHER CONCERNS THAT SHOULD BE ADDRESSED

In addition to those described above, Providence has several 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. And, 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.
- We question the breadth of the prohibition on data sharing for ACOs that fall below the mandatory review threshold and outside the safety zone (item (5) in the list of conduct that ACOs should avoid). The agencies indicate that an ACO's provider participants should not share competitively sensitive pricing or "other data" that they could use to set prices "or other terms" for services they provide outside the ACO, but the reality of any ACO model is that to effectively manage care or control costs, provider participants will need to engage in extensive data sharing on virtually all aspects of their services. For this reason, we believe that the proscribed conduct should be limited to sharing of data which is done for the primary purpose of setting prices outside the ACO, and should not be interpreted to reach data sharing intended or used for other purposes.

- The rural exception is too narrow. Having a larger share of providers where necessary should be allowed under the exception if the providers are nonexclusive (available to work with others).

Providence recognizes the complexity and importance of establishing a functional framework for agency antitrust analysis to ensure the integrity of the MSSP and to protect beneficiaries and consumers. It is our hope that the agencies can make the necessary revisions to this proposed statement such that potential ACO applicants will not be deterred from moving forward. We thank you for the opportunity to provide our comments on the proposed Statement. For more information, please contact Steve Brennan, System Director, Public Policy & Research, at (425) 525-3717 or via e-mail at steve.brennan@providence.org.

Sincerely,

John Koster, M.D.
President and Chief Executive Officer
Providence Health & Services