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Quest Diagnostics

May 30, 2011

Submitted through https://ftcpublic.commentworks.com/ftc/acoenforcementpolicy

Federal Trade Commission
Office of the Secretary
Room H-113 (Annex W)
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 Madam or Sir:

On behalf of Quest Diagnostics Incorporated, I am pleased to respond to your Request for Comments on the "Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program" (Matter V100017) in accordance with the Notice and Request for Comments published in the April 19, 2011 Federal Register.

Quest Diagnostics is the world's leading provider of diagnostic testing, information and services that patients and doctors need to make better health care decisions. Quest Diagnostics is a HIPAA covered entity that provides clinical and anatomic laboratory testing services for patients nearly 150 million times each year as ordered by hundreds of thousands of physicians and approximately one-half the hospitals in the United States. The Company offers the broadest access to diagnostic testing services through its national network of laboratories and patient service centers and approximately 43,000 employees, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is a nationwide supplier of laboratory services to the Medicare program, billing Medicare Part B directly for those services through Medicare provider numbers issued to Company-owned laboratories that are certified in accordance with the regulations promulgated under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA").

The Company also provides healthcare organizations and clinicians with information technology products that improve patient care and medical practice, through its MedPlus subsidiary and its Care360™ suite of products, Care360 Data Exchange, and the ChartMaxx® electronic document management system for hospitals. Through these products, the Company offers access to a large national healthcare provider network, including approximately 160,000 networked physicians.

The Care360 EHR system has received ONC-ATCB 2011/12 certification as a Complete EHR from the Certification Commission for Health Information Technology and is the first certified, commercially available EHR system to include the Direct Project specifications established under the coordination of the Office of the National Coordinator for Health Information Technology (ONC).

INTRODUCTORY COMMENTS

As the leading national supplier of clinical laboratory services to the Medicare program, Quest Diagnostics supports the adoption of innovative delivery mechanisms, such as Accountable Care Organizations (ACOs), to improve quality and patient safety, while realigning Medicare incentives to reduce over-utilization. We share your goals of providing better care for individuals and for populations and, at the same time, lowering growth in Medicare expenditures. Laboratory services are a key driver for improving health care quality by providing physicians with the information that they need to diagnose or monitor disease or other medical conditions, and to screen populations to detect disease, disease precursors or other conditions at the earliest possible stage when they are more curable.

Laboratory information is valuable at the patient level, to assist the treating physician in selecting appropriate tests and providing information to assist the physician in choosing among potential treatments, monitoring patient health and for other purposes. At the same time, aggregated laboratory information is extraordinarily valuable at the population level for tracking utilization, discerning trends, and providing population level insights.

Our comments on the Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program are intended to raise issues about your proposed enforcement approach that might interfere with the goals of achieving better care and lower expenditures.

Comments on Proposed Statement

Because of the multiplicity of proposed rules and / or statements of policy, our general comment is that the FTC, CMS and OIG should protect patients, physicians, and competition by collectively ensuring that ACOs or dominant ACO Participants do not explicitly or implicitly utilize access to the ACO network or allocation of shared savings or losses to influence referrals from ACO Participants to certain preferred or exclusive suppliers or to punish ACO participants for their choice of suppliers of ancillary services.

1. FTC Waivers of Antitrust Protections

FTC should not exercise enforcement discretion related to ACOs that utilize ACO participation / access to shared savings as a lever to reduce competition in the relevant ancillary services markets. The FTC should address the potential for unlawful consolidation

of the laboratory and other ancillary services markets by virtue of consolidation of laboratory and other orders from hospitals and ACO Providers who participate in an ACO. In addition, the FTC should protect the beneficiary's right of free access to providers and suppliers by prohibiting ACO or ACO Participant conduct that seeks to create and enforce exclusive or preferred arrangements with ancillary service providers.

The Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program raises concerns with regard to market consolidations through ACO formation that will lead to decreased competition, decreased patient access to medical services, and lower quality of population healthcare.

First, an ACO or a dominant ACO Participant could utilize the distribution of shared savings (or even simple market dominance created by ACO control) to consolidate laboratory test referrals to an ACO Participant's laboratory (such as a hospital laboratory) or to an exclusive or "preferred" laboratory, to the exclusion of all other laboratories. We note that the proposed statement of antitrust enforcement policy raises concerns about "anti-steering" provisions in ACO arrangements with commercial payers and believe it should be equally applicable to Medicare referrals. Arrangements to consolidate laboratory referrals would immediately reduce patient access to laboratory services – particularly in the ambulatory market, which depends on access to patient services centers where patients' specimens are collected and which are convenient to the physicians' offices. In the long run, this would lead to market consolidation, particularly in rural markets, and potential elimination of all competing ancillary services.

The proposed Statement of Antitrust Enforcement Policy provides several instances of conduct that an ACO should avoid when the ACO falls below the mandatory review threshold but outside the safety zone. An ACO in this category may be subject to Agency investigation if it engages in certain anticompetitive conduct as outlined in several bullets beginning on page 21898 of the Proposed Statement. We have two concerns. The first bullet is rather complex and difficult to understand, since the sentence is written as a "double negative." We believe it would be simpler to state that the conduct the ACO should avoid is (for example) entering into contractual or other arrangements with commercial payers intended to require or encourage the payer's commercial patients to choose only providers that participate in the ACO (i.e. steerage and perhaps other conduct related to the other listed contractual provisions). With regard to the fourth bullet, we believe the proscribed conduct should explicitly refer to restricting a commercial payer's ability to make available to its enrollees information on the ACO's cost, quality, efficiency and performance information if such information is similar to the cost, quality, efficiency and performance information used in the Shared Savings Program.

2. CMS/OIG Waiver Designs in Connection with ACOs

CMS and the OIG should avoid overly-broad waivers related to distributions and / or activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program, which inadvertently may permit conduct that

would otherwise be unlawful and ultimately harmful to beneficiaries, population health care, and honest competition. The FTC should take such waivers into account when evaluating the anti-competitive impact of ACOs.

The joint CMS / Office of Inspector General (OIG) Request for Comments on "Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center" provides for waivers of the self-referral and anti-kickback laws for: "distributions of shared savings received by an ACO from CMS under the Medicare Shared Savings Program: (1) To or among ACO Participants, ACO Providers / Suppliers, and individuals and entities that were ACO Participants or ACO providers suppliers during the year in which the shared savings were earned by the ACO; or (2) for activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program." The anti-kickback law would also provide for waivers relating to "[a]ny financial relationship between or among the ACO, ACO Participants, and ACO Providers / Suppliers necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program that implicates the Physician Self-Referral Law and fully complies with an exception at 42 CFR 411.355 through 411.357."

We raise the concern that overly-broad waivers related to distributions and / or "activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program" may inadvertently permit conduct that would otherwise be unlawful and ultimately harmful to beneficiaries, population health care, and honest competition, such as payment of remuneration in return for the opportunity to be a provider to the ACO's beneficiaries and to receive Medicare, as well as non-Medicare referrals - essentially situations where an ancillary provider tries to "buy" its way in to an ACO. This concern is <u>not</u> abated by reason of the distributions and / or the financial arrangements created by such distributions being justified as "necessary for and directly related to the ACO's participation and operations under the Medicare Shared Savings Program" (see CMS/OIG proposed rule), since unlawful incentives can lead to poor quality choices for choosing ancillary providers – decisions based on financial and not quality considerations.

We strongly believe that waivers of CMP, anti-kickback and physician self-referral laws could inadvertently lead to abusive conduct by ACOs and / or ACO Participants that could eliminate competition by health care providers or suppliers, reduce access for beneficiaries, and decrease quality of care. We believe that in some geographic locations, the ultimate outcome will be to eliminate all but ACO Providers / Suppliers from the Medicare program, contrary to the spirit of the Social Security Act, Sec. 1802(a) [42 U.S.C. 1395a] which states that "[a]ny individual entitled to insurance benefits under this title may obtain health services from any institution, agency, or person qualified to participate under this title if such institution, agency, or person undertakes to provide him such services." For example, we raise the following concerns:

1) An ACO or ACO Participant may seek to condition ACO participation by ACO providers on exclusive use of the ACO or ACO Participant's existing specialty services (such as

surgical facilities, physician specialty services, or the ACO Participant's own in-house ancillary services such as clinical laboratory, anatomic pathology or radiology services). The unlawful "remuneration" for ACO providers to limit their otherwise free choice of facilities or ancillary services is to preserve or increase Medicare or non-Medicare referrals and the potential for obtaining Medicare shared savings.

2) An ACO may distribute (or an ACO Participant may seek to redistribute or vote to distribute) a disproportionate share of shared savings in a manner intended to influence referrals by the ACO Participants and / or a reduced share to "punish" ACO providers that violate codes of conduct promulgated by the ACO with regard to their referrals outside the ACO.

3) Some ACOs may require or may choose ACO Providers / Suppliers based on their willingness to forfeit a share of shared savings that they might otherwise be eligible to receive, as a condition for receiving ACO referrals.

4) Some ACOs may require or may choose ACO Providers / Suppliers to be "exclusive" or "preferred" providers to the ACO on the basis of their willingness to make cash or in-kind contributions to the ACO to help fund ACO operations or may require suppliers to share a percentage of ACO losses (even though suppliers do not generate orders for services). Such exclusive or preferred status may in some cases extend to non-Medicare referrals for ACOs that have arrangements with commercial health plans.

In the preamble to the "Medicare Shared Savings Program: Accountable Care Organizations" proposed rule at pages 19552-3 of the April 7, 2011 Federal Register, CMS states: "To address the risk of inappropriate cost-shifting within Medicare and other Federal health care programs, we are considering prohibiting ACOs and their ACO Participants from conditioning participation in the ACO on referrals of Federal health care program business that the ACO or its ACO Participants know or should know is being provided to beneficiaries who are not assigned to the ACO." We support CMS in prohibiting that conduct as well as similar ACO conditions for participation that might be placed on ACO providers to limit referrals to non-preferred suppliers or conditions for suppliers to participate in ACOs as a "preferred" or "exclusive" supplier.

CONCLUSION

We strongly believe that the anti-kickback and related laws (including the self-referral laws) and the antitrust laws promote honest and fair competition and provide physicians and Medicare beneficiaries with the broadest range of choices for access to quality health care. Waivers of such laws to allow conduct as described above and other unknown scenarios, would, in our view, reduce access to services for beneficiaries assigned to ACOs and could reduce overall health care quality, since referrals could essentially be "steered" to a single source which has little incentive to maintain appropriate or adequate quality or service levels. Furthermore, the impact of such closed-door arrangements would have a chilling effect on competition and would, over time,

create highly concentrated systems which will become increasingly anti-competitive. Therefore, we believe that requests for a supplier to make "donations" of money, items or services to the ACO or ACO Participants at less than fair market value should not be the subject of waivers of the anti-kickback or self-referral laws. Finally, we raise concern about waivers that may result in unintended adverse consequences, such as waivers of self-referral prohibitions that result in increased utilization, as we are seeing over the past few years with physician self-referral of advanced diagnostic imaging, anatomic pathology, physical therapy, and radiation therapy services.

Quest Diagnostics appreciates the opportunity to provide its response to the Request for Comments on "Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program." As the leading national supplier of clinical laboratory services to the Medicare program, Quest Diagnostics supports the adoption of innovative delivery mechanisms that will provide better care for individuals, better health for populations, and lower growth in expenditures. Laboratory services provide physicians with health information that, in conjunction with intelligent and progressive use of health information technology, will lower costs while increasing quality of health care for individuals and populations. Our comments raise concerns about provisions that might interfere with the goals of achieving better care and lower expenditures.

Please feel free to contact me if you have any questions concerning our comments or if we can be of further assistance, at (973) 520-2225 or at Dermot.V.Shorten@QuestDiagnostics.com. Also, we would be happy to discuss this submission in person with you.

Sincerely,

Dermot Shorten
Vice President, Office of the Chairman
Quest Diagnostics Incorporated